Cell Therapy Catapult UK Clinical Trials Database 2015

Name of Sponsor	Project Title	Project Summary	Clinical Database Numbers	Lead Institution/ Company and Collaborator Partners	Clinical Trial Status	Trial Phase	Year Trial Started	Recruitment Target	Cell Type	Cell Source	Autologous/ Allogeneic	Gene Modification/ Gene Therapy	Disease area	Indication	Contact
Great Ormond Street Hospital NHS Trust / University College London	Gene therapy for SCID-X1 using a self-inactivating (SIN) gammaretroviral vector.	Gene therapy for SCID-X1. Autologous haematopoietic stem cells transplanted after modification with a self-inactivating gammaretroviral vector expressing the human common cytokine receptor gamma-chain gene.	2007-000684-16	Great Ormond Street Hospital, London	Recruiting	Phase I/II	2011	10	CD34 and/or CD133 stem cells	Blood	Autologous	Yes	Blood	X-linked severe combined immunodeficiency	Havinder Hara or Cecile Duret Clinical Project Manager UCL Institute of Child Health London h.hara@ucl.ac.uk or c.duret@ucl.ac.uk
Great Ormond Street Hospital NHS Trust	Phase I/II, non-controlled, open-label, non-randomised, single-centre trial to assess the safety and efficacy of EF1αS-ADA lentiviral vector mediated gene modification of autologous CD34+ cells from ADA-deficient individuals	Lentiviral gene therapy for ADA-SCID. Autologous haematopoietic stem cells transplanted after modification with a lentiviral vector expressing the human ADA gene.	2010-024253-36; NCT01380990	Great Ormond Street Hospital, London	Recruiting	Phase I/II	2012	10	CD34 and/or CD133 stem cells	Blood	Autologous	Yes	Blood	Adenosine Deaminase Deficiency	Havinder Hara or Cecile Duret Clinical Project Manager UCL Institute of Child Health London h.hara@ucl.ac.uk or c.duret@ucl.ac.uk
The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust	Autologous Stem Cells, Chondrocytes or the Two?	A comparison of Autologous Chondrocytes Implantation (ACI) versus existing techniques for knee cartilage repair.	UK CRN 12383	Keele University (Sponsor), Robert Jones & Agnes Hunt Orthopaedic Hospital NHS Trust (Host organisation); Arthritis Research UK; Orthopaedic Institute Ltd.	Recruiting	Phase II	2005	120	Mesenchymal stem/stromal cells	Other	Autologous	No	Bone and cartilage	Chondral/ osteochondral defects	Professor James Richardson, Institute of Orthopaedics, Robert Jones & Agnes Hunt Orthopaedic Hospital, Oswestry, SY10 7AG
Joint UCLH and UCL Biomedical Research Unit (UK)	Phenotype of autologous cells in non-union fractures	PACINO: Autologous cell therapy of fracture nonunion – cell phenotype as a predictor of outcome.	ISRCTN09755245; UK CRN 11523	University College London	In follow-up	Phase II	2011	60	Mesenchymal stem/stromal cells	Bone marrow	Autologous	No	Bone and cartilage	Bone regeneration and healing (orthopaedics)	Prof David Marsh (CI) Dr Michelle Korda (trial manager) michelle.korda@ucl.ac.uk
Azellon Ltd	A Prospective Open-Label Study to Evaluate the Safety of Cell Bandage (Mesenchymal Stem Cells) in the Treatment of Meniscal Tears	Autologous mesenchymal stem cells (MSCs) for knee meniscal repair. MSCs grown on biological scaffold for 2 weeks then surgically implanted.	2010-024162-22	Azellon Cell Therapeutics	Recruiting	Phase I/II	2012	10	Mesenchymal stem/stromal cells	Bone marrow	Autologous	No	Bone and cartilage	Knee meniscus repair	Professor Anthony Hollander, (CSO at Azellon); University of Bristol (anthony.hollander@bristol.ac.uk)
Christie Hospital NHS Foundation Trust	A Phase II Trial to Assess the Activity of NY-ESO-1 Targeted T Cells in Advanced Oesophagogastric Cancer	A Phase II trial to assess the activity of NY-ESO-1 targeted T cells in advanced oesophagogastric cancer. Gene modified T cells expressing an engineered TCR to recognise NY-ESO-1 cancer antigen.	NCT01795976; UK CRN 14133; 83343031	The Christie NHS Foundation Trust, Manchester, UK (Treatment centre and 6 other sites across EU); Cellular Therapeutics Ltd, UK - IMPD manufacturing	Recruiting	Phase II	2014	up to 28 patients	T cells	Blood	Autologous	Yes	Cancer	Advanced oesophagogastric cancer	Prof Robert Hawkins (The Christie NHS Foundation Trust) / Ryan Guest (Cellular Therapeutics Ltd)
University College London	Immunotherapy with CD19ζ gene-modified EBV-specific CTLs after stem cell transplant in children with high-risk acute lymphoblastic leukaemia	Patients with high-risk B cell precursor acute lymphoblastic leukaemia are treated with donor-derived EBV-specific cytotoxic T-lymphocytes transduced with the SFGαCD19-CD3ζ retroviral vector following allogeneic haematopoietic stem cell transplantation.	NCT01195480	CR UK and UCL Cancer Trials Centre	Recruiting	Phase I/II	2012	75	T cells	Blood	Allogeneic	Yes	Cancer	Acute lymphoblastic leukaemia	CD19 trial coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ, United Kingdom. Tel: 0207 679 9327 ctc.cd19@ucl.ac.uk
King's College London	Phase I Trial: T4 Immunotherapy of Head and Neck Cancer	Patients with locally advanced/ recurrent head and neck cancer will receive autologous gene-modified by intratumoral injection in this Phase 1 dose escalation study. T-cells will be engineered to co-express a broadly reactive ErbB-targeted CAR with a chimeric cytokine receptor that allows ex-vivo expansion of cell products using IL-4.	NCT01818323	Guy's and St Thomas' NHS Foundation Trust	In set-up	Phase I	2014	30	T cells	Blood	Autologous	Yes	Cancer	Locally advanced/ recurrent disease for which no suitable alternative therapy is available	John Maher King's College London, john.maher@kcl.ac.uk
Dendreon Corporation	An open-label study of sipuleucel-T in European men with metastatic, castrate resistant prostate cancer	An open-label study of sipuleucel-T in European men with metastatic, castrate resistant prostate cancer.	2011-001192-39	Barts London Hospital	Recruiting	Phase II	2012	45	Antigen presenting cells	Blood	Autologous	No	Cancer	Metastatic, castrate resistant prostate cancer	Abi Foreshew, ECMC, Barts Cancer Institute (Clinical Trials Practitioner)
Cell Medica Ltd.	A Phase I/II clinical trial to investigate the safety of adenovirus-specific T-cells given to high-risk paediatric patients post allogeneic haematopoietic stem cell transplant (HSCT) to treat reactivation of adenovirus.	Adoptive T cell therapy for the reconstitution of immunity to adenovirus (ADV) in paediatric patients following bone marrow transplantation.	2011-001788-36	Cell Medica , 3 UK sites	Recruiting	Phase I/II	2012	15 treated patients	T cells	Blood	Allogeneic	No	Cancer (Haematology)	ADV in paediatric patients following bone marrow transplantation	Karen Hodgkin, Cell Medica (karen.hodgkin@cellmedica.co.uk)
Cell Therapy Catapult	WT1 TCR Gene Therapy for Leukaemia: A Phase I/II Safety and Toxicity Study (WT1 TCR-001)	WT1 TCR gene therapy for leukaemia: a phase I/II safety and toxicity study (WT1 TCR-001).	2006-004950-25 NCT01621724	University College London	Recruiting	Phase I/II	2012	18	T cells	Blood	Autologous	Yes	Cancer (Haematology)	Acute myeloid leukaemia; chronic myeloid leukaemia	Zahid Sattar Cell Therapy Catapult 12th Floor, Tower Wing, Guy's Hospital Great Maze London SE1 9RT zahid.sattar@ct.catapult.org.uk
University College London	CMV TCR Gene Therapy: A Phase I Safety, Toxicity and Feasibility Study of Adoptive Immunotherapy with CMV TCR-transduced Donor-derived T cells for Recipients of Allogeneic Haematopoietic Stem Cell Transplantation	CMV TCR Gene Therapy: A Phase I Safety, Toxicity and Feasibility Study of Adoptive Immunotherapy with CMV TCR-transduced Donor-derived T cells for Recipients of Allogeneic Haematopoietic Stem Cell Transplantation.	UK CRN 12518 ; 2008-006649-18	UCL	Recruiting	Phase I	2013	10	T cells	Other	Allogeneic	Yes	Cancer (Haematology)	CMV seronegative HSCT donors & CMV seropositive HSCT recipients	Dr Emma Morris e.morris@ucl.ac.uk or Rachel Richardson University College London Institute of Immunity and Transplantation Rowland Hill Street Hampstead London NW3 2PF UNITED KINGDOM Tel: 020 7794 0500 Ext: 34932 r.richardson@ucl.ac.uk
University College London	Immunotherapy with CD25/71 Allodepleted T-cells (ICAT)	Adoptive Immunotherapy with CD25/71 allodepleted donor T-cells to improve immunity after unrelated donor stem cell transplant (ICAT) .	UK CRN14779 ; NCT01827579	CR UK and UCL Cancer Trials Centre	Recruiting	Phase II	Expected Q1 2014	24	T cells	Blood	Allogeneic	No	Cancer (Haematology)	Acute leukaemia	ICAT trial coordinator Cancer Research UK & UCL Cancer Trials Centre 90 Tottenham Court Road London W1T 4TJ UNITED KINGDOM Tel: 0207 679 9327 ctc.icat@ucl.ac.uk

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Cell Medica Inc.	A PHASE 2 OPEN LABEL STUDY TO INVESTIGATE THE EFFICACY OF AUTOLOGOUS EBV-SPECIFIC T-CELLS FOR THE TREATMENT OF PATIENTS WITH AGGRESSIVE EXTRANODAL NK/T CELL LYMPHOMA (ENKTCL)	Autologous EBV specific T-cells for treatment of EBV+ve lymphomas.	NCT01948180	Cell Medica/ 24 clinical sites, US, UK, Fr, De and SK	Recruiting	Phase II	2015	35	T cells	Blood	Autologous	No	Cancer (Haematology)	NK/T cell lymphoma	Karen Hodgkin, Cell Medica (karen.hodgkin@cellmedica.co.uk)
Cell Therapy Catapult	A Phase I/II study of the safety and efficacy of gene-modified WT1 TCR therapy in patients with Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukaemia (AML)	A single arm Phase I/II study of the safety and efficacy of gene-modified WT1 TCR therapy in patients with myelodysplastic syndrome (MDS) or acute myeloid leukaemia (AML) with low blast counts failing to achieve an IWG defined response following azacitidine therapy.	2014-003111-10	University College Hospital London	In set-up	Phase I/II	2015	25	T cells	Blood	Autologous	Yes	Cancer (Haematology)	Myeloidysplastic Syndrome and Acute Myeloid Leukaemia	Zahid Sattar Cell Therapy Catapult 12th Floor, Tower Wing, Guy's Hospital, Great Maze Pond London, SE1 9RT
University College London	COBALT: Evaluation of CAR19 T-cells as an Optimal Bridge to Allogeneic Transplantation	The purpose of this study is to administer novel cluster of differentiation antigen 19 (CD19) specific Chimeric Antigen Receptor T-cells (CAR19 T-cells) to patients with relapsed or resistant Diffuse Large B Cell Lymphoma (DLBCL) to assess the safety and efficacy of this strategy as a bridge to allogeneic transplantation.	NCT02431988	University College London Hospital	In set-up	Phase I	2015	12	T cells	Blood	Autologous	Yes	Cancer (Haematology)	Diffuse Large B-Cell Lymphoma	COBALT trial coordinator ctc.cobalt@ucl.ac.uk
University College London	CARPALL: Immunotherapy with CD19 CAR redirected T-cells for high risk, relapsed paediatric CD19+ acute lymphoblastic leukaemia and other haematological malignancies.	The purpose of this study is to evaluate the safety, efficacy and duration of response of a novel cluster of differentiation antigen 19 (CD19) specific Chimeric Antigen Receptor T-cells (CD19CAR T-cells) to paediatric patients with high risk acute lymphoblastic leukaemia (ALL) and other haematological malignancies.	2015-001144-10	Leading: 1-University College London Institute of Child Health/ Great Ormond St Hospital. Collaborators: 2- University College London Hospitals 3- Royal Manchester Children's Hospital	In set-up	Phase I	2015	18	T cells	Blood	Autologous	Yes	Cancer (Haematology)	Paediatric Acute Lymphoblastic Leukaemia and other haematological malignancies (e.g. Burkitt's lymphoma)	CARPALL trial coordinator ctc.carpall@ucl.ac.uk
UK Stem Cell Foundation/ Heart Cells Foundation	Randomised Controlled Clinical Trial of the Use of Autologous Bone Marrow Derived Progenitor Cells to Salvage Myocardium in Patients With Acute Anterior Myocardial Infarction	Autologous bone marrow derived mononuclear cells for acute myocardial infarction. Combines stem cell delivery with primary angioplasty within 5 hours post event .	NCT00765453	Barts Health NHS Trust, Queen Mary University of London, University College London	In set-up	Phase I/II	2007	70	Bone marrow mononuclear cells	Bone marrow	Autologous	No	Cardiovascular	Acute myocardial infarction	Professor Anthony Mathur William Harvey Research Institute Queen Mary University (a.mathur@qmul.ac.uk)
Queen Mary University of London	The effect of intracoronary reinfusion of bone marrow-derived mononuclear cells (BM-MNC) on all cause-mortality in acute myocardial infarction	Autologous bone marrow derived mononuclear cells for dilated cardiomyopathy, delivered via intracoronary injection.	UK CRN15079; NCT01569178	Barts Health NHS Trust, Queen Mary University of London	In follow-up	Phase II	2011	180 (3000)	Bone marrow mononuclear cells	Bone marrow	Autologous	No	Cardiovascular	Acute myocardial infarction	Professor Anthony Mathur William Harvey Research Institute Queen Mary University (a.mathur@qmul.ac.uk)
Imperial College London	A Phase I/II safety and tolerability dose escalation study following the autologous infusion of expanded adult haematopoietic stem cells to patients with established myocardial ischaemia.	Expanded adult haematopoietic stem cells for autologous infusion to patients with myocardial ischaemia.	2006-000280-28	Imperial College London	Recruiting	Phase I/II	2011	42	CD34 and/or CD133 stem cells	Bone marrow	Autologous	No	Cardiovascular	Localised myocardial dysfunction	Anne Bradshaw Imperial College Healthcare NHS Trust (anne.bradshaw@imperial.nhs.uk; 0203 313 2056)
ReNeuron Limited	A Phase I Ascending Dose Safety Study Of Intramuscular CTX0E03 In Patients With Lower Limb Ischaemia	CTX stem cells for the treatment of Lower Limb Ischaemia (Safety study).	EudraCT: 2011-005810-13 : NCT01916369	Ninewells Hospital, Dundee	Recruiting	Phase I	2014	9	Neural	Tissue	Allogeneic	No	Cardiovascular	Peripheral Arterial Disease- lower limb ischaemia	Dr John Sinden, ReNeuron Ltd info@reneuron.com
United Bristol Healthcare NHS Trust	Transplantation of enriched autologous bone-marrow derived CD 133 cells in patients having coronary surgery after STEMI: a double blind placebo-controlled trial	Transplantation of enriched autologous bone-marrow derived CD 133 cells in patients having coronary surgery after STEMI: a double blind placebo-controlled trial.	65630838 ; UKCRN 4434	Bristol Royal Infirmary	In follow-up			60	CD34 and/or CD133 stem cells	Bone marrow	Autologous	No	Cardiovascular		Dr Chris Rogers Bristol Royal Infirmary Marlborough Street Bristol Somerset BS2 8HW UNITED KINGDOM Tel: 0117 342 2507 chris.rogers@bristol.ac.uk
Dompé s.p.a.	A Phase 2/3, Multicentre, Randomized, Double-blind, Placebo-controlled, Parallel Assignment Study to Assess the Efficacy and Safety of Reparixin in Pancreatic Islet Auto-transplantation	A Phase 3, multicentre, randomized, double-blind, parallel assignment study to assess the efficacy and safety of Reparixin in pancreatic islet transplantation.	NCT01967888	Dompé	Recruiting	Phase III	2013	10	Pancreatic islets	Other	Allogeneic	No	Diabetes	Type 1 diabetes complicated by recurrent severe hypoglycaemia	Prof James Shaw Institute of Cellular Medicine Newcastle University
University of Newcastle upon Tyne	Biomedical / psychosocial islet cell transplant outcomes	Biomedical and psychosocial outcomes of islet transplantation within the NHS clinical programme.	UK CRN 4166	Newcastle University	Recruiting	Phase III	2007	100	Pancreatic islets	Other	Allogeneic	No	Diabetes	Type 1 diabetes complicated by recurrent severe hypoglycaemia	Prof James Shaw Institute of Cellular Medicine Newcastle University
Newcastle upon Tyne Hospitals NHS Foundation Trust	Treatment of LSCD using cultured limbal epithelium expanded ALSC	Autologous cultured human limbal epithelium for limbal stem cell deficiency (ophthalmology).	2011-000608-16 ; 51772481 ; UK CRN 11185	Newcastle University	In follow-up	Phase II	2012	24	Corneal	Tissue	Autologous	No	Eye	Limbal stem cell deficiency	Professor Francisco C Figueiredo Newcastle University
Scottish National Blood Transfusion Service; NHS Lothian	Pilot Clinical Assessment of Ex Vivo Expanded Corneal Limbal Stem Cell Transplantation in Patients with Severe Ocular Surface Disease (OSD) Arising from Limbal Stem Cell Deficiency	Corneal stem cells (allogeneic limbal epithelial stem cells on amniotic membrane).	2010-024409-11 ;54055321 ;UK CRN 11350	NHS Lothian, Scottish National Blood Transfusion Service	In follow-up	Phase I/II	2011	20	Corneal	Tissue	Allogeneic	No	Eye	Corneal stem cell deficiency	Prof Baljean Dhillon
Ocata Therapeutics	A Phase I/II, Open-Label, Multi-Centre, Prospective Study to Determine the Safety and Tolerability of Sub-retinal Transplantation of Human Embryonic Stem Cell Derived Retinal Pigmented Epithelial (hESC-RPE) Cells in Patients With Stargardt's Macular Dystrophy (SMD)	Retinal pigment epithelial cell replacement for Stargardt's disease.	NCT01469832	Ocata Therapeutics	In follow-up	Phase I/II	2011	12	Retinal	Human embryonic stem cell	Allogeneic	No	Eye	Stargardt's disease	Dr. James Bainbridge Moorfields Eye Hospital London (j.bainbridge@ucl.ac.uk)

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The University of Birmingham	Repeated Autologous infusions of Stem cells in Cirrhosis (REALISTIC)	A multicentre, phase II, open label, randomised controlled trial of repeated autologous infusions of G-CSF mobilised CD133+ bone marrow stem cells in patients with liver cirrhosis.	UK CRN 11288; 2009-010335-41; ISRCTN91288089	The University of Birmingham, the University of Edinburgh	In follow-up	Phase I/II	2014	81	CD34 and/or CD133 stem cells	Bone marrow	Autologous	No	Liver	Liver Cirrhosis	Prof Stuart Forbes University of Edinburgh Centre for Regenerative Medicine MRC Edinburgh EH16 4TJ UNITED KINGDOM stuart.forbes@ed.ac.uk
The University of Edinburgh	Macrophage Therapy for Liver Cirrhosis (MATCH)	A multicentre, phase I/II trial of repeated infusions of autologous CD14+ monocyte-derived macrophages in patients with liver cirrhosis.	2015-000963-15	The University of Edinburgh, SNBTS, NHS Lothian, Cell Therapy Catapult	In set-up	Phase I/II	2015	37	Bone marrow mononuclear cells	Bone marrow	Autologous	No	Liver	Liver Cirrhosis	Prof Stuart Forbes University of Edinburgh Centre for Regenerative Medicine MRC Edinburgh EH16 4TJ UNITED KINGDOM stuart.forbes@ed.ac.uk
Newcastle upon Tyne Hospitals NHS Foundation Trust	Autologous Tolerogenic Dendritic Cells for Rheumatoid and Inflammatory Arthritis	Patients with inflammatory arthritis with active involvement of a knee joint undergo leukapheresis. Monocytes are positively selected and differentiated into tolerogenic dendritic cells over the course of 7 days. The tolerogenic dendritic dendritic cells are then arthroscopically injected into the inflamed knee following saline wash-out. Primary outcomes are safety and tolerability. Biomarkers will be measured in synovial membrane biopsies and peripheral blood (baseline and +14 days). In this ascending dose study we will study one, three and ten million tolerogenic DCs (3 patients per cohort) and there is also a placebo cohort who receive saline washout only. Follow-up is for thirteen weeks post administration of tolerogenic DCs.	NCT01352858; 87426082 ; UK CRN 12108	Newcastle University	Recruiting	Phase I	2011	12	Antigen presenting cells	Blood	Autologous	No	Musculoskeletal	Rheumatoid and Inflammatory Arthritis	Prof John Isaacs Newcastle University Institute of Cellular Medicine Framlington Place Newcastle Upon Tyne Tyne and Wear NE1 7RU UNITED KINGDOM Tel: 0191 2225337 j.d.isaacs@ncl.ac.uk
Innovacell Biotechnologie AG	Skeletal muscle-derived cell implantation for the treatment of faecal incontinence: a multicentre, randomized, double-blind, placebo-controlled, parallel-group, dose-finding clinical study	Ongoing clinical trial for clinical investigation of aSMDC therapy of FI with the research medicinal product ICEF15. Objective of the study is to find the optimal cell count for functional regeneration of the external anal sphincter. The study is planned as a multinational, multicentre, randomized, double-blind, placebo-controlled, parallel-group, clinical study. A maximum of 252 female and male patients with external anal sphincter weakness or sphincter damage suffering from FI will be investigated to achieve 207 evaluable datasets. Patients are randomized to one of three groups: cell dose 1, cell dose 2, placebo (which consists of cell-free medium). Observation period is 6 months post treatment. All patients perform electrical stimulation for a total of 8 weeks, 4 weeks after biopsy and prior to implantation and 4 weeks starting immediately after implantation.	2010-021463-32	ICTA company (CRO) / University College London Hospitals	Recruiting	Phase II	2013	252	Skeletal Muscle	Other	Autologous	No	Oral and Gastrointestinal	Faecal Incontinence	Susanne Hörl Clinical Project Manager Innovacell Biotechnologie AG Mitterweg 24 6020 Innsbruck Austria
Cook MyoSite	A Prospective Nonrandomized Study of Autologous Muscle Derived Cell (AMDC) Transplantation for Treatment of Faecal Incontinence	The aim of this clinical study is to investigate the safety and feasibility of Autologous Muscle Derived Cells (AMDC; a preparation of a patient's own cells) injection into the anal sphincter for treatment of patients with faecal incontinence.	NCT01600755	Royal Hospital of London, National Centre for Bowel Research & Surgical Innovation	Recruiting	Phase I/II	2012	30	Skeletal Muscle	Other	Autologous	No	Musculoskeletal	Faecal Incontinence	Mette Aamand Sørensen +45 56868942 mette.aamand@cookmedical.com
University College London	Autologous Stem Cells in Achilles Tendinopathy	This study is looking at a new treatment, using the patient's own stem cells (the repair cells of the body), to see whether this can help reduce pain and promote healing of the Achilles tendon, without side effects.	NCT02064062	Royal National Orthopaedic Hospital	In set-up	Phase II	2014	10	Mesenchymal stem/stromal cells	Other	Autologous	No	Musculoskeletal	Achilles Tendinopathy	Andy Goldberg Royal National Orthopaedic Hospital
Imperial College	Stem cells in rapidly evolving active multiple sclerosis	Stem cells in rapidly evolving active multiple sclerosis (STREAMS).	UK CRN 13496; NCT01606215; 2012-002357-35	Imperial College London	In follow-up	Phase II	2012	13	Mesenchymal stem/stromal cells	Bone marrow	Autologous	No	Neurological	Relapsing remitting multiple sclerosis/ secondary progressive multiple sclerosis/ primary progressive multiple sclerosis	Anne Bradshaw Imperial College Healthcare NHS Trust (anne.bradshaw@imperial.nhs.uk; 0203 313 2056)d.wilkie@imperial.ac.uk
University of Cambridge	An Open Label Study to Assess the Safety and Efficacy of Neural Allo-Transplantation With Foetal Ventral Mesencephalic Tissue in Patients With Parkinson's Disease	Foetal brain tissue transplant for Parkinson's disease (TRANSEURO: An Innovative Approach for the Treatment of Parkinson's Disease).	NCT01898390	Cambridge University	Recruiting	Phase I/II	2012	40: 20 transplanted patients, 20 controls	Neural	Tissue	Allogeneic	No	Neurological	Parkinson's disease	Natalie Valle Guzman Transeuro Trial Manager University of Cambridge Danielle Daft Clinical Trials Manager University of Cambridge,
ReNeuron Limited	A Phase I Safety Trial of CTX0E03 Drug Product Delivered Intracranially in the Treatment of Patients With Stable Ischemic Stroke	CTX stem cells for the treatment of stroke disability (PISCES).	EudraCT: 2008-000696-19 : NCT01151124	Glasgow Southern General Hospital	In follow-up	Phase I	2010	11	Neural	Tissue	Allogeneic	No	Neurological	Stroke disability	Dr John Sinden ReNeuron Ltd info@reneuron.com

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ReNeuron Limited	A Phase II Simon Optimal Two Stage Efficacy Study of Intracerebral CTX0E03 DP in Patients with Stable Paresis of the Arm Following an Ischaemic Stroke	CTX stem cells for the treatment of stroke disability (PISCES II).	EudraCT: 2012-003482-18 : NCT02117635	Glasgow Southern General Hospital	Recruiting	Phase II	2014	41	Neural	Tissue	Allogeneic	No	Neurological	Stroke disability	Dr John Sinden ReNeuron Ltd info@reneuron.com
Cardiff University	Safety and feasibility of neural transplantation in early to moderate Huntington's disease in the UK.	Safety and feasibility of neural transplantation in early to moderate Huntington's disease in the UK.	UKCRN 3827	Cardiff University	In set-up	Phase I	Expected 2014	60	Neural	Other	Allogeneic	No	Neurological	Neurological	Prof Stephen Dunnett The Brain Repair Group School of Biosciences Cardiff University Museum Avenue Cardiff CF10 3AX South Wales, UK
University of Cambridge/Cardiff University	TRANSEURO Open Label Transplant Study in Parkinson's Disease	The Transeuro Transplant study is a trial which will involve grafting foetal tissue into the brain of patients with Parkinson's disease, who are already been followed in the observational study. The tissue inserted in the brain is to help replace and rebuild lost dopamine from the brain due to Parkinson's disease.	NCT01898390	University of Cambridge	Recruiting	Phase I	2013	20	Foetal Brain	Other	Allogeneic	No	Neurological	Neurological	Prof Roger Barker University of Cambridge Prof Dunnett Cardiff University
Athersys, Inc.	Phase II Trial of MultiStem in Adults with Ischemic Stroke	Double-Blind, Randomized, Placebo-Controlled, Phase 2 Safety and Efficacy Trial of MultiStem® in Adults With Ischemic Stroke.	2012-005749-18, NCT01436487	The Newcastle upon Tyne Hospitals, NHS Foundation Trust, University Hospital of North Staffordshire, University of Glasgow - Southern General Hospital, University of Glasgow - Western Infirmary, University College London Hospitals - Thames Stroke Research Network, St. Georges Healthcare NHS Trust	In follow-up	Phase II	2014	35 (140)	MultiStem® (multipotent adult progenitor cells)	Bone marrow	Allogeneic	No	Neurological	Ischemic stroke	Robert W Mays Athersys, Inc.
North Bristol NHS Trust	Repeat Infusion of Autologous Bone Marrow Cells in Multiple Sclerosis (SIAMMS-II)	The purpose of this study is to test the safety of repeated bone marrow stem cell infusion in patients with MS. We want to find out what effects, good and/or bad, it has on you and your disability. The results of a previous safety study of bone marrow stem cell infusion in patients with MS raised the possibility of some early partial repair; measurements of the speed of neurological impulses in the brain and spinal cord improved. The current study seeks to determine whether those benefits have persisted and whether they can be repeated or enhanced by repeating the procedure.	NCT01932593	Sir Halley Stewart Trust	Recruiting	Phase I	2014	6	Bone marrow mononuclear cells	Bone marrow	Autologous	No	Neurological	Multiple Sclerosis	claire.rice@nbt.nhs.uk heather.williams@nbt.nhs.uk
North Bristol NHS Trust	Assessment of Bone Marrow-derived Cellular Therapy in Progressive Multiple Sclerosis (ACTiMuS)	We have previously performed a preliminary safety study of bone marrow stem cell infusion in a small number of patients with MS. The results raised the possibility of some early partial repair; measurements of the speed of neurological impulses in the brain and spinal cord improved. The current trial is a more comprehensive study to examine whether this was a true result and help us to understand the mechanisms involved so that we can further improve therapy for MS.	NCT01815632 / ISRCTN27232902	Silverman Family Foundation, Medical Research Council	Recruiting	Phase II	2014	80	Bone marrow mononuclear cells	Bone marrow	Autologous	No	Neurological	Multiple Sclerosis	claire.rice@nbt.nhs.uk heather.williams@nbt.nhs.uk
The European Blood and Marrow Transplant Group (EBMT)	Autologous stem cell transplantation international Crohn's disease trial	Autologous CD34+ haematopoietic cells for Crohn's disease.	2005-003337-40 ; ISRT39133198 ; UK CRN 7107	European Group for Blood and Marrow Transplantation (EBMT)	In follow-up	Phase II/III	2006	45	CD34 and/or CD133 stem cells	Bone marrow	Autologous	No	Oral and Gastrointestinal	Crohn's disease	Prof Hawkey NDDC West Block, E Floor University Hospital, QMC, Nottingham NG7 2UH (cj.hawkey@nottingham.ac.uk) Miranda Clark Trial Coordinator: (astic@nottingham.ac.uk)
Guy's and St Thomas' NHS Foundation Trust	Safety and Efficacy Study of Regulatory T Cell Therapy in Liver Transplant Patients (ThRIL)	This is a clinical trial in patients undergoing liver transplantation. Research has shown that regulatory T-cells can induce tolerance to the graft in laboratory animals that have undergone organ transplantation. In this study, liver recipients will receive a single infusion of TR002, a cell therapy product that consists of regulatory T-cells that are grown and purified from the patients' own blood. The trial aims to explore the feasibility, safety, and efficacy of TR002 as add-on immunosuppressive treatment in the context of liver transplantation.	NCT02166177, UK CRN 16775	Kings College Hospital	Recruiting	Phase I/II	2014	26	T cells	Blood	Autologous	No	Oral and Gastrointestinal	End-Stage Liver Disease	Alberto Sanchez-Fueyo Gavin Whitehouse
TxCell	A Phase IIb, Multicentre, Randomised, Double-blinded, Placebo-controlled, Multi-dose and Multi-injection, Parallel Groups Study to Evaluate the Efficacy and the Safety of Ovasave in Patients With Active Refractory Crohn's Disease	The investigational product, named Ovasave (Ova-Treg), is a cell-based therapy, consisting of an autologous antigen-specific regulatory type 1 T lymphocyte expanded population administered via the intravenous route as an infusion. The study is a multicentre, randomised, double-blinded, placebo-controlled, multi-dose and multi-injection study, followed with a 16-week phase with either the possibility for an open-label treatment part or a safety follow-up part with no injection. Then, the patients will be followed in an additional long-term safety follow-up, of maximum duration of 3 years from the first administration.	NCT02327221	Cambridge University Hospital, St Mark's Hospital, Guy's and St Thomas' NHS Foundation Trust, University College London, Southampton General Hospital	Recruiting	Phase II	2014	160	T cells	Blood	Autologous	No	Oral and Gastrointestinal	Crohn Disease	Miguel Forte Nathalie Clerget clinical@txcell.com

Cell Therapy Catapult UK Clinical Trials Database 2015

Name of Sponsor	Project Title	Project Summary	Clinical Database Numbers	Lead Institution/ Company and Collaborator Partners	Clinical Trial Status	Trial Phase	Year Trial Started	Recruitment Target	Cell Type	Cell Source	Autologous/ Allogeneic	Gene Modification/ Gene Therapy	Disease area	Indication	Contact
Guy's and St Thomas' NHS Foundation Trust	The ONE Study UK Treg Trial (ONETreg1)	A study to assess cell therapy as a treatment to prevent kidney transplant rejection. The trial will involve purification of naturally occurring regulatory T cells (nTregs) from living-donor renal transplant recipients. The cells will then be grown in the laboratory and re-infused into the patient five days after the kidney transplant. This trial is part of an international European Union funded consortium aimed at evaluating cellular immunotherapy in solid organ transplantation (The ONE Study). It is anticipated that immune regulation induced by nTreg therapy can eventually be used to reduce the need for conventional immunosuppression in transplant recipients.	NCT02129881	King's College London	Recruiting	Phase I/II	2014	12	T cells	Blood	Autologous	No	Renal and Urogenital	End-stage kidney disease	Dr Rachel Hilton Guy's and St Thomas' NHS Foundation Trust
University College, London	Clinical Trial of Stem Cell Based Tissue Engineered Laryngeal Implants (RegenVOX)	This study aims to test a new ground-breaking treatment for narrowing of the voicebox and upper windpipe, which can be due to injury, inflammatory disease or cancer treatment. The new treatment tested by this study is an implant that will partially replace the voicebox or upper windpipe in order to cure the narrowing. The implant is based on a human donor voicebox or windpipe that has been processed with detergents and enzymes in order to remove all the cells from the donor, leaving a 'scaffold' of connective tissue. The patient's own stem cells are removed from the bone marrow, then are grown on the scaffold in the laboratory. These cells will form the cartilage in the wall of the scaffold. A split skin graft from the patient may be needed to line the inside of the implant. Once these cells have attached and started to grow on the scaffold, it is ready to be implanted into the patient, and an operation is performed which occurs in two separate stages. The final stage of the operation involves removing the narrow section of voicebox or upper windpipe and implanting the scaffold to reconstruct it. Patients will be followed up for two years after this operation, with investigations such as CT scans, examination of the voicebox and windpipe with a flexible camera (bronchoscopy) and blood tests performed at specific times.	NCT01977911	University College, London	In set-up	Phase I/II	2015	10	Bone marrow mononuclear cells	Bone marrow	Autologous	No	Respiratory	Ear, Nose and Throat	Martin Birchall University College London
Cell Therapy Catapult	Decellularised cadaveric tracheal scaffold recellularised with autologous mesenchymal stromal cells (MSCs)	This is a "first in human" study in patients with tracheal stenosis. The study that aims to assess the safety and initial efficacy of a tracheal transplant, consisting of a tissue engineered de-cellularised tracheal scaffold seeded with autologous mesenchymal cells. Human cadaveric tracheal tissues is harvested and processed to remove all donor cells, leaving a scaffold of connective tissue. The subject's own stem cells are removed from their bone marrow and grown on the scaffold in the laboratory. The damaged trachea is removed from the subject and the de-cellularised scaffold is implanted in its place.	2015-002108-10	University College London / Videregen	In planning	Phase I	Expected 2015	4	Mesenchymal stem/stromal cells	Bone marrow	Autologous	No	Respiratory	Tracheal Stenosis and Tracheomalacia	Martin Birchall University College London Gareth Wright Cell Therapy Catapult 12th Floor Tower Wing Guy's Hospital Great Maze Pond SE1 9RT
Athersys, Inc.	A Phase 1/2 Study to Assess the Safety and Efficacy of MultiStem® Therapy in Subjects with Acute Respiratory Distress Syndrome	A Phase 1/2 Study to Assess the Safety and Efficacy of MultiStem® Therapy in Subjects with Acute Respiratory Distress Syndrome.	2015-001586-96	University College London Cell Therapy Catapult	In set-up	Phase I/II	Expected 2015	40	MultiStem® (multipotent adult progenitor cells)	Bone marrow	Allogeneic	No	Respiratory	Acute Respiratory Distress Syndrome	Michael Aperghis Cell Therapy Catapult 12th Floor Tower Wing Guy's Hospital Great Maze Pond SE1 9RT
King's College London	A prospective phase I/II study to evaluate allogeneic mesenchymal stromal cells for the treatment of skin disease in children with recessive dystrophic epidermolysis bullosa.	A prospective phase I/II study to evaluate allogeneic mesenchymal stromal cells for the treatment of skin disease in children with recessive dystrophic epidermolysis bullosa.	2012-001394-87; 46615946 ; UK CRN 13068	Guy's hospital	In follow-up	Phase I/II	2013	10	Mesenchymal stem/stromal cells	Bone marrow	Allogeneic	No	Skin	Recessive dystrophic epidermolysis bullosa	Professor John A. McGrath Guy's Hospital Great Maze Pond London SE1 9RT UNITED KINGDOM Tel: 02071886409 john.mcgrathf@kcl.ac.uk
King's College London and Guy's & St Thomas' NHS Foundation Trust	Phase I study of COL7A1 gene-modified autologous fibroblasts in adults with recessive dystrophic epidermolysis bullosa.	Phase I study to evaluate whether intradermal injections of COL7A1 gene-modified autologous fibroblasts are safe in adults with recessive dystrophic epidermolysis bullosa.	Eudract: 2014-004884-19	King's College London	In set-up	Phase I	2015	5 to 10	Fibroblasts	Tissue	Autologous	Yes	Skin	Recessive dystrophic epidermolysis bullosa	Professor John A. McGrath Guy's Hospital Great Maze Pond London SE1 9RT UNITED KINGDOM Tel: 02071886409 john.mcgrathf@kcl.ac.uk