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GAMECHANgER-1 trial: Suppressor cells for dialysis patients to help get a kidney transplant

Submission date 09/07/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 20/07/2021	**Overall study status** Ongoing	
Last Edited 27/01/2025	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Kidney transplantation is the best treatment for patients with kidney failure. Donor organs are allocated using various criteria, one of which is the presence of antibodies (Ab) against tissue antigens called HLA, which indicate whether potential recipients will mount an aggressive rejection response against a particular donor. Organs are not offered if any of the Ab react against a prospective donor so dialysis patients with multiple Abs (~1/3rd on the transplant list) can wait a long time for a suitable donor. Although specialised treatment to allow Ab to be ignored in the allocation process is sometimes available, more powerful drugs to suppress the immune system must be used and patients still suffer high rates of rejection. This study will test a new personalised approach to improve outcomes for this group with multiple Ab, using the patient's own specialised white blood cells with natural suppressive properties (called 'regulatory T cells' (Tregs)) that we will purify and grow-up in the laboratory before infusing them back into the patient.

Who can participate?
Adults over 18 years, with kidney failure requiring transplant.

What does the study involve?
First, in Part 1, we will study the way cells from these patients respond to HLA proteins. If we see a specific pattern of response in at least 21 patients, we will invite these patients into Part 2, in the order in which they were identified. The first 9 patients will be asked to donate extra blood to test in Part 1, the results of which will allow us to better interpret the overall results at the end. In stage 1 of part 2, Tregs will be administered to the first 12 patients. After assessing the responses of these, we will then administer Tregs to the remaining 9 patients in stage 2. We will determine whether Tregs change the numbers and subtypes of Tregs circulating in the patients and suppress the responses of patient cells to HLA proteins. This study will inform us whether Tregs are capable of suppressing responses to HLA in dialysis patients with multiple Abs and thus is a potential strategy for testing in larger trials.

What are the possible benefits and risks of participating?
Participants will be required to travel to Guy’s Clinical Research Facility for the T-reg infusion and reasonable travel expenses will be reimbursed.

Leukapheresis is similar to dialysis, and side effects can include blood loss, dizziness, the need for venous access, discomfort and infection at the site of venepuncture. We will try to minimise risks by combining leukapheresis with a dialysis session.
The general risks of Treg therapy are similar to blood transfusion, and include allergic reactions ranging from mild (fevers, itching etc occurring in up to 3%) to severe and potentially life-threatening (difficulty breathing, low blood pressure, heart rhythm problems and lung inflammation (all rare occurring in fewer than one in 100,000).

Where is the study run from?
1. King's College London (UK)
2. Guy's and St Thomas' NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2021 to February 2026

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof. Alberto Sanchez-Fueyo, sanchez_fueyo@kcl.ac.uk
Dr Lusine Hakobyan@kcl.ac.uk, lusine.hakobyan@kcl.ac.uk

Contact information

Type(s)
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Type(s)
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Additional identifiers

EudraCT/CTIS number
2021-001664-23

IRAS number
1003748

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1003748

Study information

Scientific Title
GAMECHANgER-1 trial: reGulatory T cells in sensitised pAtients to iMprovE outComes after HLA-Ab iNcompatiblE Renal transplantation

Acronym
GAMECHANgER-1

Study objectives
To determine whether adoptive transfer of regulatory T cells (Tregs) into Human Leucocyte Antigen (HLA) sensitised patients can suppress memory T and B cell responses against specific HLA antigens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/11/2021, Oxford REC A (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8013; oxforda.rec@hra.nhs.uk), ref: 21/SC/0253

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
End-stage renal failure patients awaiting transplantation with antibodies against human leukocyte antigens

Interventions
Current intervention as of 23/02/2022:
Part 1:
Visit 1 (all patients):
Consent and registration will involve a check of eligibility criteria, including whether there have been negative viral tests within the last 5 years, whether there have been LFTs and ECG within the last 3 months, and whether a woman is of child-bearing age.
If no extra eligibility checks are needed, then a blood sample will be for dual Fluorospot monitoring and record demographic data, medical and transplant history (age, date of birth, sex, race, cause of kidney failure, significant past medical history, time on dialysis, potential routes of sensitisation, CRF). If extra eligibility checks are needed (ECG, LFTs, virology, pregnancy) take these at this visit, post-consent. Once eligibility is confirmed, demographic data, medical and transplant history (as above) will be recorded and blood for baseline Fluorospot test will be taken as soon as practically possible.
If possible, we will take the blood when patients are on dialysis. Some of the patients recruited may have had the same assay performed as part of a separate, ongoing observational study; in these patients, if the assay was performed 12 or fewer months before recruitment to GAMECHANgER-1, the result of this assay may be used for GAMECHANgER-1 and a further blood sample may not be needed.

Visit 2 (all patients):
Patients will be informed of the results of the Fluorospot test and whether they meet inclusion criteria for Part 2. If the recruit is not eligible for Part 2, this is end of study and all study procedures finish. If the recruit has a fluorospot pattern meeting inclusion criteria for Part 2, then they will be informed that they may be called for immunomonitoing.
Any AEs that are reported as related to study procedures (i.e. blood taking) will be recorded.

The remaining visits in Part 1 are only for the 9 recruits undergoing baseline immunomonitoring. This will begin once it is clear that the funder's milestone 1 has been met (either after 75 patients have been recruited or 12 months, whichever occurs first) or, once we have >21 recruits with eligible fluorospot patterns for Part 2.

Visit 3 (week 'zero', the next convenient dialysis session after inclusion fluorospot for phase 2 and milestone 1 is confirmed):
Vital signs (pulse, BP, temp)– record in patient notes
Blood sample for baseline immunomonitoring– fluorospot, HLA Ab, Treg numbers and phenotype
Record any AE's that are reported as related to study procedures (i.e. blood taking)

Visit 4 (1 week ±1 dialysis session after visit 3):
Vital signs (pulse BP, temp)– record in patient notes
Blood sample for baseline immunomonitoring– fluorospot, HLA Ab, Treg numbers and phenotype
Record any AE's that are reported as related to study procedures (i.e. blood taking)

Visit 5 (2 weeks ±1 dialysis session after visit 3):
Vital signs (pulse BP, temp)– record in patient notes
Blood sample for baseline immunomonitoring– fluorospot only
Record any AE's that are reported as related to study procedures (i.e. blood taking)

Visit 6 (4 weeks ±1 dialysis session after visit 3):
Vital signs (pulse BP, temp)– record in patient notes
Blood sample for baseline immunomonitoring – fluorospot, HLA Ab, Treg numbers and phenotype
Record any AE's that are reported as related to study procedures (i.e. blood taking)

Visit 7 (8 weeks ±2 dialysis sessions after visit 3):
Vital signs (pulse BP, temp)– record in patient notes
Blood sample for baseline immunomonitoring – Fluorospot, HLA Ab, Treg numbers and phenotype
Record any AE's that are reported as related to study procedures (i.e. blood taking)

Pre-Part 2 eligibility re-check:
All patients identified as having eligible fluorospot for part 2 will be seen prior to the start of Part 2 to re-check full eligibility criteria for Part 2. This may involve repeating ECG and LFTs (if no clinical test results are available within the last 3 months) and will involve re-confirming a negative pregnancy test in all women of childbearing age.
At this visit, all females of childbearing potential and males with partners of childbearing potential must re-confirm their commitment to using highly effective methods of contraception in Part 2 of the study. Additionally, demographic data will be updated where appropriate, a physical exam will be performed and vital signs (pulse, BP and temperature) will be recorded in the patients notes, and any AE's that are reported, to date as related to study procedures up to that point (i.e. blood taking) will be recorded.

Part 2:
Visit 1:
Leukapheresis will take place at a time point specified by the order of recruitment and at a time convenient for the patient. Vital signs (pulse BP and temperature) will be monitored during leukapheresis.
As per the EU Tissues and Cells Directive, a sample for serology testing will also be collected at the time of leukapheresis or, if not possible, within 7 days of leukapheresis. Mandatory serological tests (Anti-HIV-1, 2, HBsAg, Anti HBc, Anti-HCV-Ab, T. pallidum-specific test) are supplemented with HTLV-I/II antibody testing.

Visit 2:
Treg infusion will take place at a time point specified by the order of recruitment once TR001 has been expanded to sufficient numbers.
Pre-TR001 infusion, AE's reported to be related to previous blood taking or leukapheresis will be recorded. Pre-TR001 administration, a blood sample for treatment immunomonitoring– fluorospot, HLA Ab, Treg numbers, and phenotype– will be obtained. This sample may be obtained at the dialysis session immediately before Treg infusion.

Immediately before and during TR001 infusion, vital signs such as pulse, temperature, BP will be monitored. The patient will be monitored closely for 1 h after the infusion and will be kept in the CRF for adverse event monitoring for 6 hours post-TR001 administration. A symptoms-directed physical examination will be conducted prior to discharge.
Full adverse event monitoring, according to the criteria set out in section 9 begins with the administration of TR001
In all the post-TR001 infusion visits, the need for a symptoms-directed physical examination and /or symptom-specific tests will be determined according to standard medical care.

Visit 3 (1 week after Treg infusion +/- 1 dialysis session):
Perform symptoms-directed physical examination if needed and record vital signs (pulse BP, temp) in patient notes
Blood sample for treatment immunomonitoring– fluorospot, HLA Ab, Treg numbers and phenotype
Send sample for FBC, U&E, LFTs, and CRP unless results available from last dialysis session
Record all AEs and IMEs including pregnancy

Visit 4 (2 weeks after Treg infusion ±1 dialysis session):
Perform symptoms-directed physical examination if needed and record vital signs (pulse BP, temp) in patient notes
Blood sample for treatment immunomonitoring– fluorospot only
Send sample for FBC, U&E, LFTs, and CRP unless results available from last dialysis session
Record all AEs and IMEs including pregnancy according to criteria set out in section 9

Visit 5 (4 weeks after Treg infusion ±1 dialysis session):
Perform symptoms-directed physical examination if needed and record vital signs (pulse BP, temp) in patient notes
Blood sample for treatment immunomonitoring– fluorospot, HLA Ab, Treg numbers and phenotype
Send sample for FBC, U&E, LFTs, and CRP unless results available from last dialysis session
Record all AEs and IMEs including pregnancy according to criteria set out in section 9

Visit 6 (8 weeks after Treg infusion ±2 dialysis sessions):
Perform symptoms-directed physical examination if needed and record vital signs (pulse BP, temp) in patient notes
Blood sample for treatment immunomonitoring– fluorospot, HLA Ab, Treg numbers and phenotype
Send sample for FBC, U&E, LFTs, and CRP unless results available from last one or two dialysis sessions
Record all AEs and IMEs including pregnancy according to criteria set out in section 9

Visit 7 (6 months after Treg infusion ±3 dialysis sessions):
Perform symptoms-directed physical examination if needed and record vital signs (pulse BP, temp) in patient notes
Blood sample for treatment immunomonitoring– fluorospot, HLA Ab
Send sample for FBC, U&E, LFTs, and CRP unless results available from last 1-3 dialysis sessions
Record all AEs and IMEs including pregnancy according to criteria set out in section 9

Visit 8 (12 months after Treg infusion ±3 dialysis sessions):
Perform symptoms-directed physical examination if needed and record vital signs (pulse BP, temp) in patient notes
Blood sample for treatment immunomonitoring– fluorospot, HLA Ab

Send sample for FBC, U&E, LFTs, and CRP unless results available from the last 1-3 dialysis sessions
Record all AEs and IMEs including pregnancy according to criteria set out in section 9
Confirm negative pregnancy tests on all women of child-bearing potential

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Previous intervention:
Part 1, post consent – Registration and eligibility check, including a baseline negative blood pregnancy test from day 0, on all women of childbearing age. If no HIV, HCV or HBV tests have been performed within 5 years, these will be performed now.

Once eligibility criteria have been confirmed, the following information will be recorded as soon as convenient (for instance at next dialysis): age, date of birth, sex, race, cause of kidney failure, significant past medical history, time on dialysis, potential routes of sensitisation, calculated reaction frequency.
A blood sample (up to 80mls) will be taken for non-routine baseline FluoroSpot to study patients' pattern of the memory responses against HLA (see below). If possible, we will take the blood when patients are on dialysis. Some of the patients recruited may have had the same assay performed as part of a separate, ongoing observational study (REC ref 16/WM/0370); in these patients, if the assay was performed 12 or fewer months before recruitment to GAMECHANgER-1, the result of this assay may be used for GAMECHANgER-1 and a further blood sample may not be needed.
The first 9 patients identified as being eligible for part 2 will undergo baseline immunomonitoring for 2 months, to acquire FluoroSpot patterns, HLA Ab and Treg numbers /phenotype data to use in the analysis of primary and secondary endpoints.
At the funder's milestone 1, which occurs either after 75 patients have been recruited or 12 months, whichever occurs first, we will assess whether we have enough patients to move to part 2. At the end of part 1 (100 patients recruited) we will have completed one of the secondary endpoints.

Part 2
This is expected to start 9 - 12 months after the first patient is recruited to Part 1. Demographic data will be updated; more specifically, details of intercurrent illnesses since enrolment to part 1, potential sensitisation events, and changes in concomitant medication will be collected. In addition, all females of childbearing potential must have had a negative pregnancy test in the week prior to leukapheresis. All females of childbearing potential and males with partners of childbearing potential must re-confirm their commitment to using highly effective methods of contraception in Part 2 of the study.

Patients will undergo leukapheresis at a time point specified by the order of recruitment and at a time convenient for the patient.
TR001 = Autologous Tregs isolated from the peripheral blood of recruits by leukapheresis, expanded ex vivo, then given as a single use named patient therapy via intravenous infusion. Cells will be subjected to quality control assessments before use. The cell dose is 5-10x10^6 cells /kg.
Adverse event monitoring begins post-leukapheresis. As per the EU Tissues and Cells Directive, a sample for serology testing will also be collected at the time of leukapheresis or, if not possible, within 7 days of leukapheresis. Mandatory serological tests (Anti-HIV-1, 2, HBsAg, Anti HBc, Anti-HCV-Ab, T. pallidum-specific test) are supplemented with HTLV-I/II antibody testing.

The first sample of blood (up to 80mls) for FluoroSpot analysis will be taken ideally within 24 hours prior to administration of TR001 or, if not possible, at the dialysis session immediately before. Where possible, to avoid the risk of fluid overload, TR001 will be administered within 24-48 hours of the next routine dialysis. Vital signs such as pulse, temperature, BP will be monitored immediately prior to administration of TR001. The patient will be monitored closely for 1 hour after the infusion and will be kept in the Clinical Research Facility for adverse event monitoring for 3 hours post-TR001 administration.

Further blood (up to 80ml) for FluoroSpot analyses will be obtained at each of the following time points:
Sample 2: 1 week (or next dialysis session closest to 1-week) post-TR001 administration
Samples 3-5: 2, 4- and 8-weeks (or dialysis sessions closest to these) post TR001 administration (±1 session for samples 3&4. ± 2 sessions for sample 5).
Samples 6-7: 6- and 12-months (or dialysis sessions closest to these) post TR001 administration (±3 sessions).
At each of these visits, it is expected that appropriate volumes of blood will be taken, as part of routine care, for FBC, Biochemistry including Liver function tests, CRP and the results of these will be recorded. Adverse events in the time since the last visit will be recorded.
Samples for exploratory mechanistic secondary endpoint analyses (flow cytometric assessment of Treg numbers and phenotype, HLA Ab) will be taken with pre-TR001 infusion sample then samples 2, 4 and 5. Additional samples for HLA Ab will be taken with samples 6 and 7.

Intervention Type
Procedure/Surgery

Primary outcome measure
The proportion of Treg-treated patients that show suppressed memory responses to specific purified HLA (chosen to match HLA Ab profiles), measured by IL-17/IFNgamma dual fluorospot, for 2 months post-treatment, in comparison to that seen in the baseline immunomonitoring group prior to intervention. Production of only one cytokine (positive at enrolment) needs to be suppressed. This will be assessed 2 months after Treg treatment in all patients in Part 2.

Secondary outcome measures
1. The proportion of sensitised dialysis patients with unregulated T & B cell anti-HLA responses assessed using IFN/IL-17 dual colour Fluorospot assays at end of Part 1.
2. The duration of suppression of HLA-specific responses by Tregs assessed using IFN/IL-17 dual colour Fluorospot assays after 12 months post-treatment.
3. The adverse events associated with Treg therapy through reporting any untoward medical occurrence by all participants of the trial.

Secondary exploratory mechanistic endpoints:
4. Changes in Treg number and phenotype comparing baseline to post-Treg treatment assessed after 12 months post-treatment follow-up completed for each patient.
5. The changes in HLA Ab profiles measured by Luminex assessed after 12 months post-treatment follow-up completed for each patient.

Overall study start date
01/04/2021

Completion date
28/02/2026

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 23/02/2022:
Part 1:
1. Adult (aged ≥18 years) dialysis patients on the renal transplant/deceased donor waiting list with HLA Ab and a CRF ≥50%
2. HLA Ab specificities corresponding to available PURE HLA protein
3. Able to give written informed consent
4. Female participants of childbearing potential* and male participants whose partner is of childbearing potential must be willing to consent that they or their partner use highly effective** contraception during Part 2 of the trial

Part 2:
Additional inclusion criteria will be confirmed:
1. Dual Fluorospot assay result to PURE HLA proteins that indicates anti-donor reactivity without evidence of suppression by CD25+ cells – the assay will most likely have been performed as part of part 1 assessment but may have been performed as part of a separate observational study, within the time frame of this study
2. Female participants of childbearing potential* and male participants whose partner is of childbearing potential must be willing to reconfirm that they or their partner use highly effective** contraception during Part 2 of the trial

*Female patients of childbearing potential are female patients who have experienced menarche and who are not post-menopausal or permanently sterilised (eg. By tubal occlusion, hysterectomny, bilateral salpingectomy). 'Postmenopausal' is defined as no menses for 12 months without an alternative medical cause. A high follicle stimulating hormone (FSH) level in the postmenopausal range may be used to confirm a post-menopausal state in women not using hormonal contraception or hormonal replacement therapy. However in the absence of 12 months of amenorrhea, confirmation with more than one FSH measurement is required.
**Highly effective methods of birth control are those with a failure rate <1% per year when employed consistently and correctly (e.g. hormonal contraception, some intrauterine devices, vasectomised partner, total abstinence). Hormonal contraception must be associated with inhibition of ovulation. Abstinence will be evaluated in the context of the usual lifestyle of the recipient. Periodic abstinence (calendar, symptothermal, post-ovulation methods), withdrawal (coitus interruptus), spermicides only, and lactational amenorrhoea method (LAM) are not acceptable methods of contraception. A female participant with a vasectomised partner must confirm that the vasectomised partner is the only sexual partner and that surgical success of the vasectomy has been medically confirmed.
All females of childbearing potential and males whose partner is of childbearing potential must be willing to use such methods if going into Part 2 and continue to use them to the end of phase 2 follow-up.

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Previous inclusion criteria as of 28/07/2021:
Part 1:
1. Adult (≥18yrs) dialysis patients on the renal transplant/deceased donor waiting list with HLA Ab and a CRF ≥50%
2. HLA Ab specificities corresponding to available PURE HLA protein
3. Able to give written informed consent

4. Female participants of childbearing potential* and male participants whose partner is of childbearing potential must be willing to consent that they or their partner use highly effective** contraception during Part 2 of the trial

Part 2:
Additional inclusion criteria will be confirmed:
1. Dual fluorospot assay result to PURE HLA proteins that indicates anti-donor reactivity without evidence of suppression by CD25+ cells – the assay will most likely have been performed as part of part 1 assessment but may have been performed as part of a separate observational study, within the time frame of this study (REC ref 16/WM/0370).
2. Female participants of childbearing potential* and male participants whose partner is of childbearing potential must be willing to reconfirm that they or their partner use highly effective** contraception during Part 2 of the trial
* Female patients of childbearing potential are female patients who have experienced menarche and who are not post-menopausal or permanently sterilised (eg. By tubal occlusion, hysterectomy, bilateral salpingectomy)
** Highly effective methods of birth control are those with a failure rate <1% per year when employed consistently and correctly (e.g. hormonal contraception, some intrauterine devices, vasectomised partner, total abstinence).

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Previous inclusion criteria:

1. Adult (≥18yrs) dialysis patients on the renal transplant/deceased donor waiting list with HLA Ab and a CRF ≥50%
2. HLA Ab specificities corresponding to available PURE HLA protein
3. Able to give written informed consent
4. Dual FluoroSpot assay result to PURE HLA proteins that indicates anti-donor reactivity without evidence of suppression by CD25+ cells – the assay will most likely have been performed as part of part 1 assessment, but may have been performed as part of a separate observational study, within the time frame of this study
5. Female participants of childbearing potential and male participants whose partner is of childbearing potential must be willing to ensure that they or their partner use highly effective contraception during the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Part 1 – N=100 for Fluorospot observations Part 2 - N=21 for treatment, with 12 in stage 1 and n=9 in stage 2.

Total final enrolment
56

Key exclusion criteria
Current participant exclusion criteria as of 23/02/2022:
Part 1
1. Living donor kidney transplant planned
2. Listed as a recipient of multi-organ transplants (i.e. combined kidney and pancreas)
3. Known HIV+ or previous HCV or HBV. If no HIV, HCV, or HBV tests within 5 years, these will be performed post-consent
4. Patient involved in other clinical trials of investigational medicinal products.
5. Active infection or history of recurrent infection. Recurrent infection defined as more than 2 confirmed infections requiring either antibiotics, antivirals, antifungals, or hospitalisation in the 6 months prior to consent.
6. Female patients of childbearing potential with a positive pregnancy test at enrolment
7. Female patients who are breastfeeding.
8. Hypersensitivity to IMP or to any of the excipients.
9. Known contraindication to the protocol-specified treatments or procedures
10. Severe liver impairment, defined as ≥Grade 3 or severely elevated ALT, AST, or total bilirubin, on bloods done within the last 3 months
11. ECG abnormalities suggesting active myocardial ischaemia or (potentially) malignant ventricular arrhythmia: ECG to have been performed within the last 3 months.
12. Patients, who in the opinion of the PI, have a medical condition, or other relevant psychological, familial or social factor that may jeopardise their health, compliance, or influence the trial integrity in any way.

Part 2
The following exclusion criteria will be re-checked at a screening visit prior to the patient entering Part 2:
1. Living donor kidney transplant planned
2. Patient involved in other clinical trials of investigational medicinal products.
3. Active infection or history of recurrent infection. Recurrent infection defined as more than 2 confirmed infections requiring either antibiotics, antivirals, antifungals or hospitalisation in 6 months prior to entering into Part 2.
4. Female patients of childbearing potential with a positive pregnancy test in the week prior to leukapheresis
5. Female patients who are breastfeeding.
6. Hypersensitivity to IMP or to any of the excipients.
7. Known contraindication to the protocol-specified treatments or procedures
8. Severe liver impairment, defined as ≥Grade 3 or severely elevated ALT, AST, or total bilirubin on bloods done within the last 3 months
9. ECG abnormalities suggesting active myocardial ischaemia or (potentially) malignant ventricular arrhythmia: ECG to have been performed within the last 3 months.
10. Patients, who in the opinion of the PI, have a medical condition, or other relevant psychological, familial, or social factor that may jeopardise their health, compliance, or influence the trial integrity in any way.

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Previous exclusion criteria as of 28/07/2021:
Part 1

1. Living donor kidney transplant planned
2. Listed as recipient of multi-organ transplants (i.e. combined kidney and pancreas)
3. Known HIV+ or previous HCV or HBV. If no HIV, HCV or HBV tests within 5 years, these will be performed post-consent
4. Patient involved in other clinical trials of investigational medicinal products.
5. Active infection or history of recurrent infection or allergy to DMSO. Recurrent infection defined as more than 2 confirmed infections requiring either antibiotics, antivirals, antifungals or hospitalisation in 6 months prior to consent.
6. Female patients of childbearing potential with a positive pregnancy test at enrolment
7. Female patients who are breastfeeding

Part 2
The following exclusion criteria will be re-checked:
1. Living donor kidney transplant planned
2. Patient involved in other clinical trials of investigational medicinal products.
3. Active infection or history of recurrent infection or allergy to DMSO. Recurrent infection defined as more than 2 confirmed infections requiring either antibiotics, antivirals, antifungals or hospitalisation in 6 months prior to entering into Part 2
4. Female patients of childbearing potential with a positive pregnancy test in the week prior to leukapheresis
5. Female patients who are breastfeeding

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Previous exclusion criteria:

1. Living donor kidney transplant planned
2. Listed as recipient of multi-organ transplants (i.e. combined kidney and pancreas)
3. Known HIV+ or previous HCV or HBV. If no HIV, HCV or HBV tests within 5 years, these will be performed post-consent
4. Patient involved in other clinical trials of investigational medicinal products
5. Active infection or history of recurrent infection or allergy to DMSO. Recurrent infection defined as more than 2 confirmed infections requiring either antibiotics, antivirals, antifungals or hospitalisation in 6 months prior to consent
6. Female patients of childbearing potential with a positive pregnancy test at enrolment
7. Female patients who are breastfeeding

Date of first enrolment
01/03/2022

Date of final enrolment
30/11/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's Hospital
Guy's and St Thomas' NHS Foundation Trust
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
St Helier Hospital
Epsom and St Helier University Hospitals NHS Trust
Wrythe Lane
Charshalton
United Kingdom
SM5 1AA

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Sponsor information

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King's College London

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Sponsor type
University/education

Website

http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
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Great Maze Pond
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England
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SE1 9RT
+44 (0)20 7188 5732
amy.holton@kcl.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/Home.aspx

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
It is intended that the results of the study will be reported and disseminated at international conferences and in peer-reviewed scientific journals. Recruiting sites will be informed of the results and will be asked to disseminate the findings to participants.
Patient groups will be informed of the results for dissemination among their members.

Intention to publish date
28/02/2027

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/04/2023	02/05/2023	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 2.0	10/10/2023	06/12/2023	No	No