ISRCTN23537803 https://doi.org/10.1186/ISRCTN23537803

Vaccination of healthy human volunteers against the minor histocompatibility antigen (mHAg) HA-1 using a DNA and MVA 'prime /boost' regimen

Submission date 03/10/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 04/10/2012	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 06/08/2024	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-vaccine-help-make-stem-cell-transplants-work-for-more-people-leukaemia-or-lymphoma

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2011-001773-99

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13063

Study information

Scientific Title
A phase I clinical trial of the vaccination of healthy human volunteers against the minor histocompatibility antigen (mHAg) HA-1 using a DNA and MVA 'prime/boost' regimen

Acronym
HA-1

Study objectives
The purpose of this vaccine study is to produce immune cells (called T-cells) which can prevent and treat leukaemias.

HA-1 is a cell surface protein expressed only selectively by blood forming cells. It is one of the best targets for the immune system to attack after blood and marrow transplant (HSCT). HSCT treats leukaemias by replacing the patient's diseased blood cells with those from a healthy matched donor. 70% of the general population have the HA-1 protein on their blood cells, the remaining 30% do not and are termed HA-1 negative. HA-1 negative individuals can be immunised against the HA-1 protein by vaccination. Following this, HA-1 specific immune cells, produced by vaccinees, can be used to kill patient cells expressing the HA-1 protein on their surface. During this study we will assess the safety and effectiveness of the HA-1 vaccine. This vaccine has two components a primer (called pDOM-HA-1) consisting of the DNA for the HA-1 and a booster vaccine (called MVA-HA-1) consisting of the HA-1 DNA attached to a different carrier.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Gene Therapy Advisory Committee (GTAC), First MREC approval date 07/12/2011

Study design
Non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

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
Vaccine to prevent and treat leukaemia

Interventions
MVA-HA-1, DNA vaccination; pDOM-HA-1, DNA vaccination

Intervention Type
Biological/Vaccine

Phase
Phase I

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
Safety and toxicity and to establish the Maximum Tolerated Dose (MTD); Timepoint(s): Continuous assessment

Secondary outcome measures
The timing and magnitude of peak HA-1-specific cytotoxic T-lymphocyte responses

Overall study start date
01/03/2009

Completion date
17/04/2018

Eligibility

Key inclusion criteria
Inclusion criteria as of 08/12/2016
1. HLA-A2+ and HA-1- genotype
2. Aged 18 years of age or over
3. Healthy male adult volunteers
4. Written informed consent given
5. WHO performance status 0-1
6. Haematological and biochemical values within normal laboratory range, or, if abnormal, not considered to be clinically significant by the Principal Investigator to prevent participation in the trial

Original inclusion criteria:
1. HLA-A2 positive and HA-1 negative.
2. 18 years of age or older
3. Donors who are no longer donating blood products and will not in the future
4. Written informed consent given

5. WHO performance status 0-1
6. Haematological and biochemical values within normal laboratory range
7. Female donors should be nulliparous and unable to have children (i.e., post-menopausal or have undergone a hysterectomy or bilateral oophorectomy)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
Planned Sample Size: 12; UK Sample Size: 12

Key exclusion criteria
Exclusion criteria as of 08/12/2016:
1. Females
2. Donors with previous adverse effects to vaccination
3. Donors on treatment with steroids/immunosuppressive drugs
4. Participants who are not willing to use an adequate method of barrier contraception for the duration of the trial treatment if engaged in sexual activity with a female of childbearing potential and for at least 28 days following the last vaccination
5. History of severe allergy
6. Participants known to be serologically positive for Hepatitis B, C or HIV
7. Previous participation in a vaccine clinical trial or participation in any clinical research in the 6 weeks prior to registration
8. Planned or possible foreign travel requiring vaccination until 28 days after the last planned study vaccination
9. Any vaccination (including the flu vaccine) 6 weeks before trial entry
10. Any planned vaccine during and 6 weeks after receiving the study vaccine
11. Any other medical condition which in the Investigator’s opinion would make the participant unsuitable for participation in this study

Original exclusion criteria:
1. Donors with previous adverse effects to vaccination
2. Donors on treatment with steroids/ immunosuppressive drugs
3. Women with a history of pregnancy
4. Pregnant or lactating women
5. History of severe allergy
6. Participants known to be serologically positive for Hepatitis B, C or HIV
7. Previous participation in a vaccine clinical trial or participation in any clinical research in the 6 weeks prior to registration
8. Planned or possible foreign travel requiring vaccination
9. Any vaccination (including the flu vaccine) 6 weeks before, during and 6 weeks after receiving the study vaccine (total 9 months)

10. Any other medical condition, which in the Investigator's opinion, would make the participant unsuitable for participation in this study

Date of first enrolment
13/12/2012

Date of final enrolment
17/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital
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Sponsor information

Organisation
University of Birmingham (UK)

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Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Bloodwise

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/03/2018

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made 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?
Other unpublished results	version 1.0	28/10/2021	01/11/2021	No	No
Plain English results			06/08/2024	No	Yes
Poster results		07/12/2017	06/08/2024	No	No