

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

Submission date 03/10/2012	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 04/10/2012	Overall study status Completed	☐ Statistical analysis plan ☒ 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

Clinical Trials Information System (CTIS)

2011-001773-99

Protocol serial number

13063

Study information

Scientific Title

A phase I clinical trial of the vaccination of healthy human volunteers against the minor histocompatibility antigen (mHA_g) 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

Primary study design

Interventional

Study design

Non-randomised study

Study type(s)

Treatment

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)

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Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

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**

United Kingdom

England

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University of Birmingham (UK)

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

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