

# Vaccination of healthy human volunteers against the minor histocompatibility antigen (mHA<sub>g</sub>) HA-1 using a DNA and MVA 'prime /boost' regimen

<b>Submission date</b> 03/10/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/10/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/08/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

### Contact name

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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<sub>g</sub>) 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

## 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?
<a href="#">Other unpublished results</a>	version 1.0	28/10/2021	01/11/2021	No	No
<a href="#">Plain English results</a>			06/08/2024	No	Yes
<a href="#">Poster results</a>		07/12/2017	06/08/2024	No	No