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The effect of inorganic nitrite on endothelial function in ischaemia-reperfusion in the human forearm

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/10/2017	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0205168931

Study information

Scientific Title
The effect of inorganic nitrite on endothelial function in ischaemia-reperfusion in the human forearm

Study objectives
To determine whether giving additional inorganic nitrite protects the lining of the blood vessels from being damaged by an interruption in the flow of blood.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised single-blind placebo-controlled cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

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
Cardiovascular

Interventions
Additional inorganic nitrite vs no additional inorganic nitrite

Intervention Type
Other

Primary outcome measure
Added 27/02/2008: Reduction in forearm endothelial dysfunction (responses to acetylcholine) due to ischaemia-reperfusion with pre-ischaemic infusion of sodium nitrite

Secondary outcome measures
Added 27/02/2008: Effect of nitrite on reperfusion

Overall study start date
02/08/2005

Completion date
01/11/2012

Eligibility

Key inclusion criteria
Added 27/02/2008:
1. Healthy subjects
2. Aged 18-45
3. Have volunteered themselves and are willing to sign the consent form

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
Added 27/02/2008:
1. Healthy subjects unwilling to consent
2. History of hypertension, diabetes or hypertensive on BP measurement
3. Pregnant or any possibility that a subject may be pregnant unless in the latter case a pregnancy test is performed with a negative result
4. History of any serious illnesses, including infectious diseases as above
5. Subjects taking systemic medication (other than the oral contraceptive pill)

Date of first enrolment
02/08/2005

Date of final enrolment
01/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barts and The London
London
United Kingdom
EC1M 6BQ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Barts and The London NHS Trust (UK)

Funder Name
Queen Mary University of London (QMUL) (UK)

Alternative Name(s)
QMUL

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration