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

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

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Other

Health condition(s) or problem(s) studied
Cardiovascular

Interventions
Additional inorganic nitrite vs no additional inorganic nitrite

Intervention Type
Other

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

Key secondary outcome(s)
Added 27/02/2008: Effect of nitrite on reperfusion

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
All

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
United Kingdom

England

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration