

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/10/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

Study design

Randomised single-blind placebo-controlled cross-over study

Primary study design

Interventional

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