Investigation of the protective effects of keratinocyte growth factor (KGF) in a human lipopolysaccharide induced model of acute lung injury

Submission date 25/04/2008	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 12/12/2008	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 19/05/2014	Condition category Respiratory	Individual participant data

Plain English summary of protocol

http://www.nres.npsa.nhs.uk/researchsummaries/?entryid29=20564&q=0%c2%ac08%2fNIR02% 2f46%c2%ac

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number 2008-000441-58

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MRC ref: G0701690; 08005DM-A

Study information

Scientific Title

Study objectives

Does treatment with a clinically relevant dose of keratinocyte growth factor (KGF) reduce pulmonary and systemic inflammation induced by lipopolysaccharide (LPS) inhalation in humans?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Health and Social Care (HSC) Research Ethics Committee (REC2), Department of Health, Social Services and Public Safety (DHSSPS), approved on 21/07/2008 (ref: 08/NIR02/46)

Study design

Prospective randomised double-blind placebo-controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Acute lung injury (ALI)

Interventions

Subjects will be randomised to palifermin 60 µg/kg per day or normal saline placebo intravenously for 3 days prior to LPS inhalation.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Keratinocyte growth factor (KGF)

Primary outcome measure

The ability of KGF to reduce alveolar inflammation, as measured by the difference in bronchoalveolar lavage (BAL) receptor for advanced glycation end products (RAGE) concentration between the KGF and placebo treated groups at 6 hours post LPS inhalation.

Secondary outcome measures

- 1. Alveolar inflammatory response at 6 hours post LPS inhalation
- 2. Plasma inflammatory response (C-reactive protein) at 24 hours post LPS inhalation
- 3. Alveolar matrix metalloproteinase activity at 6 hours post LPS inhalation
- 4. Intracellular signalling in the alveolar space at 6 hours post LPS inhalation
- 5. Indices of alveolar epithelial and endothelial function and injury at 6 hours post LPS inhalation

Overall study start date

01/08/2008

Completion date

01/08/2011

Eligibility

Key inclusion criteria

Healthy subjects, both males and females

Participant type(s)

Patient

Age group

Adult

Sex Both

Target number of participants 36

Key exclusion criteria

 Age <18 years
 Pregnancy, breast-feeding or women of childbearing potential not using adequate contraception
 Serum amylase above upper limit of normal
 Consent declined

Date of first enrolment

01/08/2008

Date of final enrolment 01/08/2011

Locations

Countries of recruitment Northern Ireland

United Kingdom

Study participating centre Intensive Care Unit Belfast United Kingdom BT12 6BA

Sponsor information

Organisation Belfast Health and Social Care Trust (UK)

Sponsor details 51 Lisburn Road Belfast Northern Ireland United Kingdom BT9 7AB +44 289 03 29241 rosemary.mcveigh@belfasttrust.hscni.net

Sponsor type Hospital/treatment centre

Website http://www.belfasttrust.hscni.net

ROR https://ror.org/02tdmfk69

Funder(s)

Funder type Government **Funder Name** Medical Research Council (UK) (ref: G0701690)

Alternative Name(s) Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type Government organisation

Funding Body Subtype National government

Location United Kingdom

Funder Name REVIVE (a charity which supports research in the intensive care unit in the Royal Victoria Hospital, Belfast) (UK)

Funder Name Northern Ireland Chest Heart and Stroke (NICHS) (UK)

Funder Name Added as of 30/12/2008:

Funder Name

Research and Development Office, Northern Ireland Health and Social Services, Central Services Agency (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/06/2014		Yes	No