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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/12/2008	**Overall study status** Completed	
Last Edited 19/05/2014	**Condition category** Respiratory	

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

Clinical Trials Information System (CTIS)
2008-000441-58

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

Completion date
01/08/2011

Eligibility

Key inclusion criteria
Healthy subjects, both males and females

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Age <18 years
2. Pregnancy, breast-feeding or women of childbearing potential not using adequate contraception
3. Serum amylase above upper limit of normal
4. Consent declined

Date of first enrolment
01/08/2008

Date of final enrolment
01/08/2011

Locations

Countries of recruitment
United Kingdom

Northern Ireland

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

Sponsor information

Organisation
Belfast Health and Social Care Trust (UK)

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, Medical Research Committee and Advisory 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

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