ISRCTN82733574 https://doi.org/10.1186/ISRCTN82733574

Towards an inhaled vaccine against pneumonia - trial of inhaled low-dose interleukin-12 as an immune potentiator to enhance natural responses against pneumococci colonising the nasopharynx

Submission date 16/01/2008	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/03/2008	**Overall study status** Stopped	
Last Edited 17/05/2017	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Stephen Gordon

Contact details
Liverpool School of Tropical Medicine
Pembroke Place
Liverpool
United Kingdom
L3 5QA
+44 (0)151 705 3169
Stephen.Gordon@lstmed.ac.uk

Additional identifiers

Protocol serial number
BAL0801

Study information

Scientific Title
Interleukin-12 as an adjuvant for mucosal vaccination against pneumococcal disease

Acronym
Mucosal IL-12 Pneumovac

Study objectives
1. Is IL-12 a safe and potentially effective adjuvant for human mucosal vaccination?
2. Will the adjuvant effect of IL-12 on mucosal defence against pneumococcus seen in animal models also be observed in studies with human experimental pneumococcal carriage?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending as of 16/01/2008:
1. The Central Office for Research Ethics Committees (National Research Ethics Service, NHS, UK)
2. Liverpool School of Tropical Medicine Research Ethics Committee

Study design
SA1: Observational study lung effects subcut IL-12
SA2: Bayesian dual endpoint phase 1 dosing trial
SA3: Open label RCT of inhaled IL-12 vs placebo and experimental pneumococcal carriage

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pneumococcal carriage, otitis media, pneumonia and invasive pneumococcal disease

Interventions
Specific aim 1 (SA1):
100 ng/kg subcutaneous IL-12 all participants (no control arm). IL-12 has been extensively phase 1 and 2 tested by this route and this is selected as a minimally toxic dose. All participants have bronchoscopy before and after to determine the pulmonary effect of subcutaneous IL-12 by paired comparison. The pulmonary measurements are the novel bit so SA1 is just an observational study of low-dose IL-12.

Specific aim 2 (SA2):
Starts at inhaled 0.25 ng/kg and proceeds in doubling measures to 2.5 ng/kg inhaled IL-12. The dual endpoints of toxicity (grade 1 symptoms only in 50% subjects) and efficacy (defined as equalling the pulmonary effect of 100 ng/kg IL-12 subcut from SA1) will be combined using a Bayesian dual endpoint trial design to obtain an optimal dose.

Specific aim 3 (SA3 - the intervention study):
Open label randomised controlled trial (RCT) comparing a single dose of inhaled IL-12 (dose defined in SA2) versus placebo. Endpoint is the effect on experimentally induced pneumococcal carriage.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Interleukin-12 (IL-12)

Primary outcome(s)
Specific Aim 1: Pulmonary markers of adjuvant activity following subcutaneous IL-12 (determination of efficacy endpoint for Specific Aim 2)
Specific Aim 2: Optimal mucosal dose of IL-12 (using dual endpoint [efficacy and toxicity] phase 1 design)
Specific Aim 3: Mucosal humoral and cellular responses to experimental pneumococcal carriage

Key secondary outcome(s))
1. Duration of pneumococcal carriage following IL-12 challenge
2. Effect of IL-12 and experimental pneumococcal carriage on susceptibility to repeat pneumococcal carriage challenge

Completion date
30/09/2011

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Aged over 18, either sex
2. Healthy volunteers
3. Normal lung function
4. Non-smokers

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Asthma
2. Any pre-existing chronic illness
3. Current ill-health
4. Pregnancy
5. Recent ex-smokers

Date of first enrolment
01/10/2008

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liverpool School of Tropical Medicine
Liverpool
United Kingdom
L3 5QA

Sponsor information

Organisation
Liverpool School of Tropical Medicine (UK)

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type

Charity

Funder Name
Wellcome Trust (UK) - funding applied for but pending, result due in mid July 2008

Funder Name
National Institute of Health Research (NIHR) Biomedical Research Centre Royal Liverpool University Hospital (UK) - partial funding obtained for staff costs for 3 years

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes