ISRCTN21133397 https://doi.org/10.1186/ISRCTN21133397

A randomised controlled trial (pilot study) of the use of macerated garlic in patients with cystic fibrosis who have pulmonary infection with Pseudomonas aeruginosa

Submission date
08/03/2007

Recruitment status
No longer recruiting

Registration date
28/03/2007

Overall study status
Completed

Last Edited
01/11/2011

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Alan Smyth

Contact details
Division of Respiratory Medicine
Clinical Sciences Building
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB
+44 (0)115 823 1703
alan.smyth@nottingham.ac.uk

Additional identifiers

Protocol serial number
P2005V3

Study information

Scientific Title

Acronym
The Garlic Against Pseudomonas (GAP) study

Study objectives
That garlic extract can inhibit quorum sensing molecules, produced by Pseudomonas aeruginosa, as measured in sputum and plasma from patients with cystic fibrosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Nottingham Research Ethics Committee 1 on the 9th November 2005 (ref: 05/Q2403/135).

Study design
Double blind, randomised, placebo controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cystic fibrosis

Interventions
1. Placebo: one capsule once daily (656.01 mg of olive oil and 9.99 mg cardamom oil) for eight weeks.
2. Garlic: one capsule once daily (656.01 mg of garlic oil macerate and 9.99 mg cardamom oil) for eight weeks.

All outcome data will be collected at the eight week visit and there will be no further follow up.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Macerated garlic

Primary outcome(s)

Levels of acyl-homoserine lactones and other quorum sensing molecules (such as quinolones) in sputum and plasma at baseline and eight weeks.

Key secondary outcome(s))
Microbiology investigations:
1. Quantitative sputum culture at baseline and eight weeks
2. Qualitative microbiology:
a. mucoid/non-mucoid phenotype at baseline and eight weeks
b. antibiotic resistance pattern - Minimum Inhibitory Concentrations (MICs) to ceftazidime and tobramycin at baseline and eight weeks
c. garlic metabolites in sputum and plasma at baseline and eight weeks

Clinical investigations:
1. Pulmonary function at baseline and eight weeks
2. Weight and height at baseline and eight weeks
3. Clinical score at baseline and eight weeks
4. Number of pulmonary exacerbations and requirement for oral and intravenous antibiotics whilst on study medication at baseline and eight weeks
5. Adverse effects and patient acceptability questionnaire at eight weeks only
6. Serum lipids, liver function, C-reactive protein, clotting and full blood count at baseline and eight weeks

Completion date
31/03/2008

Eligibility

Key inclusion criteria
The following patients with cystic fibrosis will be eligible:
1. Chronic pulmonary infection with P. aeruginosa
2. Can produce sputum
3. Are able to swallow the capsules
4. Over eight years
5. Are not currently suffering from an acute pulmonary exacerbation, requiring oral or intravenous antibiotics
6. Patients consent or parental consent with childs assent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria

1. Prolonged clotting or platelet count below 150 x 10^9/L at baseline
2. Abnormal liver function
3. Pregnant or lactating mothers

Date of first enrolment
01/04/2007

Date of final enrolment
31/03/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Division of Respiratory Medicine
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Industry

Funder Name
EU Marie Curie Fellowship (UK)

Funder Name

Boots (UK)

Funder Name
University of Nottingham Institute of Clinical Research (UK)

Funder Name
NHS Research & Development (Nottingham City Hospital) (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	01/04/2010		Yes	No