

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	☒ Prospectively registered ☐ Protocol
Registration date 28/03/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/11/2011	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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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).

Primary study design

Interventional

Study design

Double blind, randomised, placebo controlled trial

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 child's assent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Prolonged clotting or platelet count below $150 \times 10^9/L$ 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