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# 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

### ClinicalTrials.gov number

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

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

### Secondary outcome measures
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

### Overall study start date
01/04/2007

### 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

### Age group
Other

### Sex
Both

### Target number of participants
30 patients: 15 less than 16 years, and 15 greater than 16 years

### 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
England

United Kingdom

### Study participating centre
**Division of Respiratory Medicine**
Nottingham
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## Sponsor information

### Organisation
University of Nottingham (UK)

### Sponsor details
c/o Dr Paul Cartledge
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### Sponsor type
University/education

### Website
http://www.nottingham.ac.uk/ris/

### 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

## 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 | 01/04/2010 | | Yes | No |