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Glutamine supplementation for cystic fibrosis

Submission date	Recruitment status	[X] Prospectively registered
22/11/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/12/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/06/2017	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2007-006204-37

Protocol serial number
2007 version 3

Study information

Scientific Title
Glutamine supplementation for cystic fibrosis

Study objectives
Will glutamine supplementation for eight weeks improve sputum and blood inflammatory markers of cystic fibrosis activity?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Nottingham Research Ethics Committee 2, 09/07/2008, ref: 08/H0408/26
Amendment approved 28/07/2008.

Study design
Parallel group placebo controlled randomised trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
1. Glutamine 21 g/day
2. Placebo

Treatment will continue for eight weeks for both. Follow up will occur for this entire period and a telephone call will be made 4 weeks later.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Glutamine supplementation

Primary outcome(s)
Change in inflammatory markers in induced sputum, measured at baseline and after eight weeks.

Key secondary outcome(s))
1. FEV1
2. Serum C-reactive protein (CRP)
3. Infectious load of Pseudomonas
4. Systemic blood neutrophil activity
5. Jensen clinical score

All outcomes measured at baseline and after eight weeks.

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Over 14 years old, male and female
2. Forced expiratory volume in one second (FEV1) greater than 40% predicted or receive regular nebulised saline treatment
3. Colonisation with Pseudomonas

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. Current pregnancy or breastfeeding
2. Recent pulmonary exacerbation in past month
3. Lung transplant
4. Recently diagnosed or uncontrolled diabetes
5. Cirrhosis or severe liver failure
6. Initiation of new pulmonary therapies in the past month

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Division of Epidemiology and Public Health
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Research organisation

Funder Name
Cystic Fibrosis Foundation (USA)

Alternative Name(s)
CF Foundation, CFF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

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	01/03/2016		Yes	No