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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

Contact name
Dr Andrew Fogarty

Contact details
Division of Epidemiology and Public Health
Clinical Science Building
Nottingham City Hospital
Nottingham
United Kingdom
NG5 1PB
+44 115 823 1713
andrew.fogarty@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number
2007-006204-37

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Change in inflammatory markers in induced sputum, measured at baseline and after eight weeks.

Secondary outcome measures
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.

Overall study start date
01/01/2008

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

Age group
Not Specified

Sex
Both

Target number of participants
44

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
England

United Kingdom

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

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
University Park
Nottingham
England
United Kingdom
NG5 1PB

Sponsor type
University/education

Website
http://www.nottingham.ac.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

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	01/03/2016		Yes	No