

Glutamine supplementation for cystic fibrosis

Submission date 22/11/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/12/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/06/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

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