

Glutamine supplementation for cystic fibrosis

Submission date 22/11/2007	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 21/12/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/06/2017	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

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