

Multicentre trial of oral calorie supplements for children with cystic fibrosis

Submission date
23/06/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
01/07/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
03/10/2017

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

Protocol serial number
PJ484

Study information

Scientific Title
Multicentre trial of oral calorie supplements for children with cystic fibrosis: a randomised controlled trial

Acronym

CALICO

Study objectives

Oral calorie supplements improve, or prevent deterioration in, body mass index centile of children with cystic fibrosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cystic fibrosis

Interventions

Oral protein energy supplements.

The control intervention involved routine dietary advice provided by the cystic fibrosis clinic dietitians, who advised on improving nutritional content of the diet using normal foods, ie not prescribing oral protein, energy supplements. The treatment group received these supplements in addition to routine dietary advice.

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Oral protein energy supplements

Primary outcome(s)

Change in body mass index centile over one year.

Key secondary outcome(s)

Other nutritional outcomes, spirometry outcomes, eating behaviour, activity levels, gastrointestinal symptoms.

Completion date

01/10/2005

Eligibility

Key inclusion criteria

Children with cystic fibrosis aged between 2-15 years who meet one of the following criteria:

1. Body mass index centile of less than 25th and more than 0.4th for age
2. No increase in body weight over the past 3 months
3. Decrease in body weight of 5% from baseline over a period of less than six months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 Years

Upper age limit

15 Years

Sex

All

Key exclusion criteria

Children were excluded if they had been diagnosed with cystic fibrosis in the previous three months, had received any form of enteral nutrition during the previous three months, had cystic fibrosis-related diabetes or liver disease, or had a forced expiratory volume at one second (FEV1) of less than 30% of that predicted for height, age and sex.

Date of first enrolment

01/07/2000

Date of final enrolment

01/10/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Institute of Child Health
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation

University of Liverpool (UK)

ROR

<https://ror.org/04xs57h96>

Funder(s)

Funder type

Charity

Funder Name

UK Cystic Fibrosis Trust research grant (Ref PJ484)

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	18/03/2006		Yes	No