ISRCTN95744468 https://doi.org/10.1186/ISRCTN95744468

Multicentre trial of oral calorie supplements for children with cystic fibrosis

Submission date	Recruitment status
23/06/2005	No longer recruiting
Registration date	**Overall study status**
01/07/2005	Completed
Last Edited	**Condition category**
03/10/2017	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled 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
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 measure
Change in body mass index centile over one year.

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

Overall study start date
01/07/2000

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

Age group
Child

Lower age limit
2 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
97

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
England

United Kingdom

Study participating centre
Institute of Child Health
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation
University of Liverpool (UK)

Sponsor details
Brownlow Hill
Liverpool
England
United Kingdom
L69 3BX

Sponsor type
University/education

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Charity

Funder Name
UK Cystic Fibrosis Trust research grant (Ref PJ484)

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	18/03/2006		Yes	No