ISRCTN85099875 https://doi.org/10.1186/ISRCTN85099875

What is the ideal dose of protein substitute in Phenylketonuria (PKU)?

Submission date	Recruitment status
12/09/2003	No longer recruiting
Registration date	**Overall study status**
12/09/2003	Completed
Last Edited	**Condition category**
12/01/2010	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
N0045113499

Study information

Scientific Title

Study objectives
Dose a lower dose of protein substitute achieve the same or better level of blood phenylalanine control when compared to the higher dosage recommended by the MRC Working Group on PKU?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised cross over prospective study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Phenylketonuria (PKU)

Interventions
Protocol A: 2 g/kg/day of protein equivalent
Protocol B: 1.2 g/kg/day protein equivalent

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
A change in blood phenylalanine levels on a lower dose of protein substitute.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2002

Completion date
30/04/2003

Eligibility

Key inclusion criteria
25 subjects with well controlled PKU aged between 2-10 years of age.

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
10 Years

Sex
Not Specified

Target number of participants
25

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2002

Date of final enrolment
30/04/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Birmingham Children's Hospital
Birmingham
United Kingdom
B4 6NH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Birmingham Children's Hospital NHS Trust (UK)

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	01/07/2006		Yes	No