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

Contact name
Dr Anita MacDonald

Contact details
Birmingham Children's Hospital
Dietetics Department
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH
+44 (0)121 333 8024
anita.macdonald@bhamchildrens.wmids.nhs.uk

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised cross over prospective study

Study type(s)
Treatment

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(s)
A change in blood phenylalanine levels on a lower dose of protein substitute.

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed

No

Age group
Child

Lower age limit
2 Years

Upper age limit
10 Years

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Birmingham Children's Hospital
Birmingham
United Kingdom
B4 6NH

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

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

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	01/07/2006		Yes	No