

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

**Submission date**  
12/09/2003

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
12/09/2003

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
12/01/2010

**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

**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?
<a href="#">Results article</a>	results	01/07/2006		Yes	No