The "online availability" study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27044

Source
Nationaal Trial Register

Brief title
N/A

Health condition

PKU

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam (AMC)
Source(s) of monetary or material Support: SHS international

Intervention

Outcome measures

Primary outcome

1. The effect of online availability of individual phenylalanine levels to patients with PKU on their plasma phenylalanine levels;

2. The effect of online availability of individual phenylalanine levels to patients with PKU on the frequency of their phenylalanine measurements.

Secondary outcome

The effect of online availability of individual phenylalanine levels to patients with PKU on the frequency.

Study description

Background summary

Rationale:

Phenylketonuria (PKU; MIM 261600) is an autosomal recessive disorder of phenylalanine metabolism caused by a deficiency of the enzyme phenylalanine hydroxylase (PAH; EC 1.14.16.1). Patients are detected by newborn screening, and treated with a protein restricted diet with supplementation of all aminoacids but phenylalanine (Phe) to prevent cerebral damage resulting from high plasma Phe levels. Adherence to the diet, resulting in acceptable Phe levels, is of great importance for the outcome of the patients. Previous reports suggest that self-management may improve dietary compliance. Patients with PKU treated in the Academic Medical Center (AMC) and Leiden University Medical Center (LUMC) already have a high degree of self-management. Patients take blood samples at home at regular intervals, for measurement of their phenylalanine (Phe) value, and send the blood-spots by mail to the laboratory. If the value is outside the recommended range they will be informed by the dietician, if not they can phone or email the dietician to obtain their value. To increase the availability of their individual Phe values to the patients and parents, without interference of a professional, we plan to give each individual patient online access to their own Phe values.

Objectives:

The aim of this study is to evaluate the effect of online availability of individual phenylalanine (Phe) levels to patients with PKU on plasma Phe levels, on the frequency of Phe measurements and on the frequency of contact with the dietician.

Study design:

We aim to perform a randomized controlled trial.

Research questions:

1. What is the effect of online availability of individual Phe levels to patients with PKU on their plasma Phe levels?;

2. What is the effect of online availability of individual Phe levels to patients with PKU on the frequency of their Phe measurements?;

3. What is the effect of online availability of individual Phe levels to patients with PKU on the frequency of the interaction with the dietician, and on the type of issues discussed with the dietician?;

Procedure:

All patients with PKU aged 1 year and older who have been detected by newborn screening and have been continuously treated with a protein restricted diet and supplementation of aminoacids, and who are treated in the AMC or the LUMC, are invited to participate in the study. The participating patients will be randomized into 2 groups: one group with online access to the Phe results, and one control group who will get online access to the results after the end of this study and will continue the present procedure for twelve more months.

Patients who have online access to their Phe results will no longer be called by the dietician about results outside the recommended range. The Phe results will be made available at their personal “My PKU” page which will contain their Phe values, a link to the Dutch guidelines on the dietary management of PKU and the possibility to send an e mail to the dietician. The plasma Phe levels and the frequency of blood sampling of each patient in the 12 months before and in the 12 months of online availability will be evaluated, both with respect to the recommended range and advised frequency for the age. In the six months before and the first twelve months of the online availability of results the dietician will register the number of patients who called to ask about their results as well as the number of patients asking for dietary advises. In the first twelve months of online availability the number of times that the database is accessed by each patient will be registered.

Study objective

Online availability of phenylalanine-levels will improve dietary compliance in patients with phenylketonuria.

Study design

N/A

Intervention

During a period of twelve months, one group will have online access to the individual

phenylalanine results and the other group will continue the present procedure. Patients who have online access to their phenylalanine results will no longer be called by the dietician about results outside the recommended range. These patients personally can adjust their diet to the phenylalalnine levels and determine the frequency of blood-sampling.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with PKU aged 1 year and older who have been detected by newborn screening and have been continuously treated with a protein restricted diet and supplementation of aminoacids.

Exclusion criteria

No access to the internet at home.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2008
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-12-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL666
NTR-old	NTR1171
Other	MEC : 07/292.
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A