

The "online availability" study.

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27044

Bron

Nationaal Trial Register

Verkorte titel

N/A

Aandoening

PKU

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam (AMC)

Overige ondersteuning: SHS international

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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 phenylalanine levels and determine the frequency of blood-sampling.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No access to the internet at home.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-04-2008
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	21-12-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A