Early diagnosis of coeliac disease in the Preventive Youth Health Care Centres in the Netherlands

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Het doel van de studie is om op de consultatiebureaus in de regio Kennemerland de haalbaarheid, kosten-effectiviteit en acceptatie van vroege opsporing naar coeliakie (door middel van case finding) bij kinderen tussen de 12 maanden en 4 jaar te...

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

Samenvatting

ID

NL-OMON20983

Bron
NTR

Verkorte titel
GLUTENSCREEN

Aandoening

Coeliac disease, Active case finding, Secondary prevention, Preventive Youth Health Care Centre.

Coeliakie, vroege opsporing, secundaire preventie, jeugdgezondheidszorg

Ondersteuning

Primaire sponsor: Leiden University Medical Center; Dutch Coeliac Patients Society; Preventive Youth Health Care Centres;
Overige ondersteuning: ZonMw, The Hague, the Netherlands
Biohit Oyj Headquarters, Helsinki, Finland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To establish the feasibility, effectiveness and costs of early case finding of CD in children attending the YHCCs in a well described region in the Netherlands, using a POC test for TG2A determination. Comparison with outcome of current health care.

Toelichting onderzoek

Achtergrond van het onderzoek

Coeliac disease (CD) is an immune-mediated systemic disorder elicited by the ingestion of gluten containing cereals (among others wheat, rye and barley) from the normal diet in genetically susceptible individuals. CD is treated with a gluten-free diet (GFD). In the Netherlands for every child diagnosed with CD, there are seven who have unrecognized, and therefore, untreated disease. This is partially due to the variable clinical presentation and symptoms, including asymptomatic.Untreated disease is associated with long-term complications, such as delayed puberty, neuropsychiatric disturbances, associated autoimmune disease, miscarriages, small-for-date-births, osteoporosis, and, rarely, malignancy. CD increases the overall mortality risk, reduces the quality of life and yields extensive negative economic consequences, thereby presenting a resource challenge for current and future health systems. Recent prospective studies show that CD develops very early in life and that treatment of CD patients detected by early diagnosis results in health improvement.The current standard health care is unable to solve the problem of underdiagnose of CD and early diagnosis and treatment may only be achieved on a large scale by mass screening or by early and active case-finding. However, the Commission Medical Ethics (CME-LUMC) found that the current evidence is insufficient to assess the balance of benefits and harms of screening for CD in asymptomatic children. So, we propose here an active case finding project in symptomatic children in a Young Health Care Centres (YHCC) regio in the Netherlands to achive secondary prevention of the disease.

In the Netherlands, more than 95% of all children aged 12 months-4 years visit the YHCC whose goal is to promote and secure the health and safety of all children, among others by early detection or prevention of diseases. Secundary prevention of CD by early case finding fits within these goals.

Doel van het onderzoek

Het doel van de studie is om op de consultatiebureaus in de regio Kennemerland de haalbaarheid, kosten-effectiviteit en acceptatie

van vroege opsporing naar coeliakie (door middel van case finding) bij kinderen tussen de 12 maanden en 4 jaar te onderzoeken. De resultaten van deze methode zullen worden vergeleken met de uitkomsten van de huidige gezondheidszorg.

Onderzoeksopzet

The determination of the specific celiac antibodies will take place during the regular monitoring of the consultation office, between the ages of 12 months and 4 years. If the result is negative, (specific celiac antibodies are not present), the antibodies will yearly be measured untill 4 years old.

Onderzoeksproduct en/of interventie

If there is one or more CD-associated symptoms present and the parents have give informed consent to participate in this study, a finger-prick on CD specific blood antibodies against the the enzyme tissue transglutaminase2 (TG2A) will be performed at the YHCC. If the POC test is positive, the child will be refered to the paediatrician gastroenterologist for further investigation for celiac disease.

Contactpersonen

Publiek

Leiden University Medical Centre
Dept. Of Pediatrics
PO box 9600
M.L. Mearin
Leiden 2300 RC
The Netherlands

Wetenschappelijk

Leiden University Medical Centre
Dept. Of Pediatrics
PO box 9600
M.L. Mearin
Leiden 2300 RC
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age 12 months to 4 years;

Not diagnosed with CD;

Not on a GFD;

One or more CD-associated symptoms are presented;

Parents have a sufficient knowledge of Dutch language.

informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No informed consent;

Asymptomatic children;

Insufficient knowledge of Dutch language and/or inability to understand the information provided; Children on a GFD.

children who are already diagnosed with CD

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	15000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-06-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52929
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7089
NTR-old	NTR7287
CCMO	NL63291.058.17
OMON	NL-OMON52929

Resultaten