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

No registrations found.

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

Summary

ID

NL-OMON20983

Source
NTR

Brief title
GLUTENSCREEN

Health condition

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

Coeliakie, vroege opsporing, secundaire preventie, jeugdgezondheidszorg

Sponsors and support

Primary sponsor: Leiden University Medical Center; Dutch Coeliac Patients Society; Preventive Youth Health Care Centres;
Source(s) of monetary or material Support: ZonMw, The Hague, the Netherlands Biohit Oyj Headquarters, Helsinki, Finland

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Children already diagnosed with CD prior to the study (n);

Time investment by medical and nursing staff at the YHCCs (sec);

Costs of the investigational strategy (time, materials) (€);

Cost-effectiveness of the investigational strategy;

Acceptance of active case finding by the Dutch population.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	15000
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-06-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52929
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results