Saliva testing for the diagnosis of reflux disease in infants

Gepubliceerd: 12-05-2014 Laatst bijgewerkt: 18-08-2022

Salivary pepsin tests can play a role in the diagnostic process of infant GERD: - by excluding GERD; and/or - by establishing GERD in an early stage of the disease and/or establish the need for further invasive testing

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28151

Bron
NTR

Aandoening

Gastroesophageal reflux, Gastro-oesophageal reflux, Gastroesophageal reflux disease, Gastro-oesophageal reflux disease, infant, pediatrics

Ondersteuning

Primaire sponsor: Academic Medical Centre, Emma Children's hospital, Amsterdam
Overige ondersteuning: funds = initiator =
sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Healthy controls:
- Salivary pepsin A concentrations at day 1

2. Symptomatic infants:
- Baseline salivary pepsin A concentrations compared to healthy controls
- Correlation of baseline salivary pepsin A concentrations with clinical outcome during standardized treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: GERD is common in infants with a prevalence of >12% in the western population. To prevent over- as well as under diagnosis and treatment of infant GERD, there is a clear need to distinguish mild GER related symptoms from pathological GERD in this large group of patients. Currently, the international guidelines propose combined pH and multichannel intraluminal impedance (pH-MII) as a diagnostic tool to assess GERD. However, normal values are lacking and it is unclear how the results of this test relate to treatment outcome. Salivary pepsin measurement has been shown a specific marker for GERD in adults and is a simple, non invasive test. The additional diagnostic and predictive value of pepsin measurement in saliva of symptomatic infants is unknown.

Objective: To test the hypothesis that salivary pepsin tests can play a role in the diagnostic process of infant GERD:

- by excluding GERD; and/or

- by establishing GERD in an early stage of the disease and/or establish the need for further invasive testing

Study design:

1. Cross sectional study in healthy control infants

2. Prospective outcome study in infants with GERD

Study population:

Healthy infants and infatns with GERD from the United Kingdom and The Netherlands

Study protocol: Saliva samples from healthy controls once. Saliva samples from symptomatic infants will be collected at standardized timepoints during a standardized diagnostic and treatment protocol.

Main study parameters/endpoints:

In healthy controls, salivary pepsin A concentrations will be determined to create a reference

range
In symptomatic infants, baseline salivary pepsin A concentrations will be compared to healthy controls and correlated with clinical outcome during standardized treatment.

Doel van het onderzoek

Salivary pepsin tests can play a role in the diagnostic process of infant GERD:

- by excluding GERD; and/or

- by establishing GERD in an early stage of the disease and/or establish the need for further invasive testing

Onderzoeksopzet

1.Healthy controls:

- IGERQ-R questionnaire at baseline. Score < 16 to qualify as a healthy control.

- Saliva samples will be collected one hour after a feed on two consecutive days using a blunt sterile plastic single use transfer pipette. Samples will be stored in refrigerator and analyzed for pepin <7 days of collection with an pepsin A specific enzymatic assay.

Symptomatic infants:

- IGERQ-R questionnaire at baseline: Score >15 to qualify as a symptomatic infant. Furthermore I-GERQ-R at day 0, day 14 and day 44. At these timepoints response is defined as follows:

* No response: I-GERQ-R above symptomatic score (>15 points) and no significant improvement (improvement in score <5 points) compared to baseline.

* Partial response: I-GERQ-R above symptomatic score (>15 points) but with significant improvement (improvement in score >4 points) in symptom score compared to baseline OR I-GERQ-R below symptomatic score (<16 points) but no significant improvement (improvement in score >4 points) in symptom score compared to baseline.

* complete response: I-GERQ-R drops below symptomatic score (<16) AND a significant improvement of score (improvement in score >4 points)

- Saliva samples will be collected one hour after a feed at presentation and after two weeks of standard conservative treatment. If the infants have no response or a partial response to this conservative therapy, saliva samples will again be collected at the end of an additional 4 weeks trial of proton pump inhibitor (PPI) treatment. Salivary pepsin will be determined using

the method described above.

- 24 hour pH-multichannel intraluminal impedance (pH-MII) will be performed when infants have no response or a partial response to 2 weeks of standard conservative treatment. Reflux index(RI), symptom index (SI), symptom sensitivity index (SSI) and symptom association probability score (SAP) will be used to determine a positive or negative result.

Onderzoeksproduct en/of interventie

2 weeks of 1 daily 1 mg/kg omeprazol therapy in symptomatic children not responding to 2 weeks of conservative treatment.

Contactpersonen

Publiek

Kinderarts MDL, AMC, H7-248
P.O. Box 22660
Marc A. Benninga
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663053 / +31 (0)20 5666297

Wetenschappelijk

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The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy controls

- Informed consent signed by caregiver(s)

- At least 34wks gestational age (GA)

- At most 24 months post natal age (PNA)

- Attending a regular health care check up at Childs health clinic or a physician for an unrelated problem

- Negative score in I-GERQ-R questionnaire

2. Symptomatic infants

- Informed consent signed by caregiver(s)

- At leaast 34wks GA

- At most 18 months post natal age (PNA)

- Attending a regular health care check up at Childs health clinic or a physician for GER related symptoms

- Positive score on I-GERQ-R questionnaire

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Known structural GI abnormalities

- Previous gastro-intestinal (GI) surgery

- Neurological syndromes and development disorders

- Any condition that would make it unsafe for the subject to participate determined by the treating physician.

- Use of anti GER medications (prokinetics, erytromycin, PPI, H2RA, antacida) in the last 5 days before inclusion.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-05-2014
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL4455
NTR-old	NTR4578
Ander register	intern onderzoeksnummer : PEP2014

Resultaten