Saliva testing for the diagnosis of reflux disease in infants

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28151

Source
NTR

Health condition

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

Sponsors and support

Primary sponsor: Academic Medical Centre, Emma Children's hospital, Amsterdam
Source(s) of monetary or material Support: funds = initiator = sponsor

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Healthy controls:

Day to day variability between samples taken at day 1 and day 2.

2. Symptomatic infants:

- Correlation of baseline salivary pepsin and pH-MII parameters after two weeks of unsuccessful (no complete response) conservative treatment

- Correlation of salivary pepsin and pH-MII parameters after two weeks of unsuccesful (no complete response) conservative treatment

- Correlation of salivary pepsin and I-GERQ-R scores at different time points.

Study description

Background summary

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.

Study objective

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.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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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.

Study design

Design

Study type:	Observational non invasive
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):	15-05-2014
Enrollment:	300
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL4455
NTR-old	NTR4578
Other	intern onderzoeksnummer : PEP2014

Study results