

Investigating the relationship between enamel defects, tooth decay, the mother's health during pregnancy and the child's health during their first year in children aged 1-3 years

Submission date 30/03/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/04/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/05/2020	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Severe dental caries (tooth decay) in very young children is a serious problem. Decay could result in children losing their milk teeth. Sometimes, milk teeth may have structural defects that weaken the tooth and make it more likely to lose enamel (the hard coating of the tooth) through decay. The health of children during their first year when the milk teeth are developing or their mother's health throughout pregnancy can affect tooth development and cause these defects. This study aims to investigate the relationship between these defects and dental caries.

Who can participate?

Children aged between 1 and 3 years

What does the study involve?

Mothers visiting medical centers will be asked to participate in this study. If they approve, their children will have a dental examination, and the mothers will be asked some general questions about their health and their children's.

What are the possible benefits and risks of participating?

There are no risks to participants because they will not receive any treatment as part of the study. The children will have a dental check-up, which might identify decay that can then be treated.

Where is the study run from?

Tishreen University (Syria)

When is the study starting and how long is it expected to run for?

April 2019 to September 2019

Who is funding the study?
Tishreen University (Syria)

Who is the main contact?
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2. Dr. Hasan Ali (hasan.h.ali@outlook.com)
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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

Protocol serial number

U1111-1230-8903

Study information**Scientific Title**

Enamel hypoplasia (EHP) as a predictive factor of early childhood caries (ECC): a cross-sectional study

Study objectives

Enamel hypoplasia could be a predictive factor of early childhood caries.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/07/2017, The Institutional Review Board of Tishreen University (Latakia, Syria; no other contact details available at present), ref: 1789

Study design

Observational cross-sectional study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Enamel hypoplasia, caries

Interventions

Mothers visiting medical centers will be asked to participate in this study. If they approve, their children will have a dental examination. Dental examination will be achieved after gentle wiping of the teeth from food remnants using cotton. One dentist will check the outer surface of the front teeth and the upper surface of back teeth (molars) in daylight against a window. In addition, mothers will be asked some general questions about their children's health status. The mother will be interviewed by the same dentist, and will be asked many question about her child's health status. Questions will relate to:

1. The type of delivery (natural or Caesarean)
2. Smoking (for the mother: yes/no)
3. Medications (for the mother throughout pregnancy, and the baby throughout the first year of life)
4. The mother's weight at the time of labour and the baby's weight immediately after birth
5. Presence of anemia during pregnancy
6. Diseases affecting the baby throughout the first year of life

These questions were developed by the research team based on the probable risk factors presented in previous similar studies.

All procedures will be done at the same time for each mother-child pair without any follow-up.

Intervention Type

Other

Primary outcome(s)

Presence of hypoplasia-associated severe early childhood caries (HAS-ECC) according to the scoring system of Caufield et al, 2012, which consists of 3 stages (0, 1 and 2, where 2 is the most severe)

Key secondary outcome(s)

Risk factors such birth weight, birth type, infectious diseases affecting the mother throughout pregnancy, or her child in their first year of life.

Completion date

30/11/2019

Eligibility

Key inclusion criteria

1. Aged between 1 and 3 years
2. Able and willing to cooperate with the examination

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 years

Upper age limit

3 years

Sex

All

Key exclusion criteria

1. Parents do not consent
2. Child has a disability or systematic disorder

Date of first enrolment

20/04/2019

Date of final enrolment

20/10/2019

Locations**Countries of recruitment**

Syria

Study participating centre**Tishreen University**

Department of Pediatric Dentistry, Tishreen University Latakia, Syria.

Latakia

Syria

00963

Sponsor information**Organisation**

Tishreen University

ROR

<https://ror.org/04nqts970>

Funder(s)**Funder type**

University/education

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Nabih Raslan (raslan.nabih@tishreen.edu.sy), from 3 months after publication up to 3 years. Data will be available for researchers who provide a methodologically sound proposal.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/02/2019	15/05/2020	Yes	No