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# 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

**Registration date**
16/04/2019

**Overall study status**
Completed

**Last Edited**
15/05/2020

**Condition category**
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
1. Dr. Nabih Raslan (rasln.nabih@tishreen.edu.sy)
2. Dr. Hasan Ali (hasan.h.ali@outlook.com)
3. Dr. Celine Al-Jalky. (celinemelad2018@gmail.com)

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# Additional identifiers

**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

**Primary study design**
Observational

**Study design**
Observational cross-sectional study

**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.
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## Sponsor information

### Organisation
Tishreen University

### ROR
https://ror.org/04nqts970

## Funder(s)

### Funder type
University/education

### Funder Name
Tishreen University

# 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 |