

Stop Caries Stockholm

Submission date 19/08/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/12/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/11/2016	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Inequalities in oral health are related to socioeconomic factors. Stop Caries Stockholm is a study in multicultural less privileged areas which aims to prevent tooth decay in preschool children by introducing a fluoride-based preventive treatment.

Who can participate?

About 4000 children are invited to participate in the study.

What does the study involve?

Children are randomly allocated to one of two groups. One group receives a fluoride varnish application on their teeth when they are 12 months old. The other group receives standard care.

What are the possible benefits and risks of participating?

The benefit is fewer dental caries in the future. No known risks exist with this protocol.

Where is the study run from?

It is a collaborative project between department of Dental Medicine and Centre for Health Equity Studies at Karolinska Institute, Public Dental Service in Stockholm, as well as private clinics.

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

April 2011 to March 2014.

Who is funding the study?

Stockholm County Council and Karolinska Institute (Sweden)

Who is the main contact?

Dr. Margaret Grindefjord
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers**Protocol serial number**

1

Study information**Scientific Title**

A caries prevention program to preschool children living in multicultural, low socio-economic areas of Stockholm

Acronym

SCS

Study objectives

Children, 1-year of age, subjected to a fluoride-based preventive program will develop fewer dental caries than children in a control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional ethics committee (EPN), January 19, 201, Dnr 2010/1956-31/4.

Study design

Cluster-randomised controlled trial with a prospective and longitudinal design

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Dental caries

Interventions

The participants are divided into two treatment arms using a cluster-randomized design. All children have their first examination at 12 month.

Children in the test group clinics receive a fluoride varnish application on their teeth on each visit in an extended program.

In the reference group clinics the children receive examinations according to the standard preventive program in Stockholm.

The examinations are repeated at 24 and 36 month in the reference group clinics and at 18, 24, 30 and 36 month in the test group clinics. Both the test group and the reference group will be examined at 84 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Dental caries - The international caries detection system (ICDAS) is used to diagnose caries. Measured at baseline, after one year, two years and after six years. In the test group the primary outcome will also be measured after one and a half year and after two and a half year.

Key secondary outcome(s)

1. Tooth brushing habits
2. Cost effectiveness
3. Caries progression

Measured at baseline, after one year, two years and after six years

Completion date

31/03/2014

Eligibility

Key inclusion criteria

All children born in 2010 living in 23 multicultural low socioeconomic areas of Stockholm are invited to participate in the study.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

Does not meet inclusion criteria.

Date of first enrolment

01/04/2011

Date of final enrolment

31/03/2014

Locations**Countries of recruitment**

Sweden

Study participating centre

Dalagatan 11

Stockholm

Sweden

SE-11324

Sponsor information**Organisation**

Stockholm County Council (Sweden)

ROR

<https://ror.org/02zrae794>

Funder(s)**Funder type**

Government

Funder Name

Stockholm County Council (Sweden)

Alternative Name(s)

Stockholm County Council

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Funder Name

Karolinska Institutet (Sweden)

Alternative Name(s)

Karolinska Institute, KI

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2016		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes