ISRCTN35086887 https://doi.org/10.1186/ISRCTN35086887

Stop Caries Stockholm

Submission date	Recruitment status	[_] Prospectively registered
19/08/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/12/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/11/2016	Oral Health	

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
Margaret.grindefjord@ftv.sll.se

Study website

http://www.stopcariesstockholm.se/

Contact information

Type(s)
Scientific

Contact name
Dr Margaret Grindefjord

Contact details
Dalagatan 11
Stockholm
Sweden
SE-11324
+46 8 12316536
margaret.grindefjord@ftv.sll.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
1. Tooth brushing habits
2. Cost effectiveness
3. Caries progression

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

Overall study start date
01/04/2011

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

Age group
Child

Sex
Both

Target number of participants
4000

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)

Sponsor details

Hantverkargatan 11
Stockholm
Sweden
SE-113 82
+46 8 12313381
kjell.bjerrehorn@sll.se

Sponsor type
Government

Website
http://www.sll.se/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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