ISRCTN36415433 https://doi.org/10.1186/ISRCTN36415433

Effect of Topacal C-5 on Enamel Remineralisation in Situ

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/05/2016	Oral Health	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr B Alshammari

Contact details
Department of Child Dental Health
Leeds Dental Institute
The Worsley Building
Clarendon Way
Leeds
United Kingdom
LS2 9LU
+44 (0)113 233 6138
r&d@leedsth.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436130443

Study information

Scientific Title
Effect of Topacal C-5 on Enamel Remineralisation in Situ

Study objectives
The aim of this study is to study the effect of Topacal C-5 which is milk protein based and fluoride free and its role in enamel remineralisation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Oral Health: Dental materials

Interventions
Randomised controlled trial: Topacal C-5 or distilled water

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Remineralisation of enamel slabs as determined using transverse microradiography and microhardness testing.

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/02/2003

Completion date
31/10/2003

Eligibility

Key inclusion criteria
Healthy adults aged 18-65 years residing in Leeds

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/02/2003

Date of final enrolment
31/10/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department of Child Dental Health
Leeds
United Kingdom
LS2 9LU

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

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