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Cellular effects and clinical effectiveness of currently prescribed doses of carbamide peroxide tooth whitening products

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 16/12/2014	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0263177895

Study information

Scientific Title
Investigation of the cellular effects and clinical effectiveness of currently prescribed doses of carbamide peroxide tooth whitening products: a randomised controlled trial

Study objectives
What is the effect of differing concentrations of carbamide peroxide tooth whitening products on the oral hard and soft tissues?

Ethics approval required
Old ethics approval format

Ethics approval(s)
University College Hospitals NHS Foundation Trust Ethics Committee, July 2006

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
Tooth whitening

Interventions
1. Treatment with whitening kits with 10% carbamide peroxide
2. Treatment with whitening kits with 16% carbamide peroxide
3. Treatment with whitening kits with 22% carbamide peroxide
4. Treatment with inactive gel
5. Treatment with 16% whitening strips carbamide peroxide

Total duration of active tooth whitening treatment was 14 days. Patient were seen for clinical assessement on Day 0 (start), Day 14 and at 3 months for final review.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Carbamide peroxide

Primary outcome measure
Current information as of 26/01/2009:
Alteration in tooth colour from the three prescribed agents (non-active placebo, 10% carbamide peroxide and 16% carbamide peroxide) during a 2 week course of tooth whitening and the overall colour stability at 3 months.

Initial information at time of registration:
1. To measure the efficacy of carbamide peroxide concentration on rate and longevity of tooth shade variation
2. To investigate the effect of currently used dosages of carbamide peroxide on human oral epithelium

Secondary outcome measures
Added 26/01/2009:
1. Soft tissue changes during the active treatment period and on subsequent review
2. Tooth senstivitiy over the active treatment period
3. Patients perceptions of tooth colour at baseline, 2 weeks and 3 months

Overall study start date
09/03/2006

Completion date
01/10/2007

Eligibility

Key inclusion criteria
Healthy volunteers (aged 19- 53 years, either sex)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Pregnant or breast-feeding women
2. Absence of systemic diseases, periodontal problems or any kind of medication or prosthesis in the regions assigned for the brush biopsy

Date of first enrolment
09/03/2006

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Eastman Dental Hospital
London
United Kingdom
WC1X 8LD

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
University College London Hospitals NHS Foundation Trust (UK)

Funder Name
NHS R&D Support Funding (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