ISRCTN34471493 https://doi.org/10.1186/ISRCTN34471493

Control of periodontal inflammation, systemic inflammatory responses and cognitive decline in Alzheimer's disease

Submission date
03/05/2013

Recruitment status
No longer recruiting

Registration date
16/08/2013

Overall study status
Completed

Last Edited
22/03/2018

Condition category
Nervous System Diseases

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] Individual participant data
- [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
An important cause of inflammation (soreness and swelling), especially in older people, is gum disease. This can be treated by improving oral health dentists can fix damaged teeth and dental hygienists can help to keep the gums healthy by cleaning and by providing advice. Some evidence suggests that inflammation is also important in Alzheimer's disease. This inflammation, both that caused by gum disease and that associated with Alzheimer's, can be measured in the blood. This study aims to find out if people with mild memory problems have inflammation that can be measured in their blood and whether improving gum health reduces that inflammation. If it does, then the next step, in another study, would be to see whether this affects the risk of getting Alzheimer's disease.

Who can participate?
People over the age of 65 who do not have dementia but do have some memory problems

What does the study involve?
People taking part in the study are randomly allocated to two groups: one receives an intensive dental treatment and the other receives usual care. They have an assessment of their memory and a blood and saliva test. Then they see a dentist and a dental hygienist. Some have regular treatment fixing any major problems with their teeth and advice about how to keep the gums healthy. Others have more intensive dental hygiene.

What are the possible benefits and risks of participating?
The possible benefits are a good assessment of tooth and gum health for all participants followed by either normal standard of care or more intensive oral health treatment. The risks are nothing more than that of having a blood test.

Where is the study run from?
This is a study at King's Health Partners, a group of hospitals including the Maudsley, King's College and Guys and St Thomas', London (UK)

When is the study starting and how long is it expected to run for?
November 2011 to November 2014

Who is funding the study?
The Biomedical Research Centres at King's Health Partners (UK)

Who is the main contact?
Professor Simon Lovestone
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Control of periodontal inflammation, systemic inflammatory responses and cognitive decline: a comparative study of standard oral care versus periodontal care

Study objectives
1. To investigate relationships between periodontal disease (and associated systemic inflammatory responses) and both progression of cognitive decline and gene expression in T cells and dendritic cells in response to such inflammatory changes.
2. To determine the feasibility of a hub and spoke-based community assessment of oral and mental health, and secondary care provision of dental treatment, for the improvement of oral health and changes in systemic markers of inflammation as a precursor to a larger intervention study to determine how this influences cognitive decline, mediated by and related to changes in lymphocyte activity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - East, 05/09/2011, ref: 11/LO/0987

Study design
Interventional randomised single-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Periodontitis and disease progression in Alzheimer's disease

Interventions
Recruited individuals are stratified for gender and randomised into either a periodontal care or a standard care group using a random number table.

Provision of oral hygiene instruction using a Braun Oral B electric toothbrush provided for the patient and supplemented by use of chlorhexidine mouthwash for one month.

Full mouth tooth and root instrumentation under local anaesthesia over 4 visits, with tailored oral hygiene reinforcement at each visit, and where necessary, removal of hopeless teeth and removal of decay and provisional restorations in decayed teeth/repair of decayed fillings

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Feasiblity and effectiveness of periodontal treatment at improving oral health in people with mild cognitive impairment (primary outcome A: changes in plaque scores, probing depths and bleeding scores), measured at 6-7 weeks

Secondary outcome measures
1. Levels of circulating proinflammatory cytokines (CRP and IL-6)
2. Rate of cognitive decline (change in CERAD score in 6 weeks; secondary outcome B change in rate of conversion to dementia over 1 year)
3. Whether there is a shared complex inflammatory marker for periodontitis and mild cognitive impairment and whether change in this marker set predicts response to therapy (shared marker set, predictive value of marker set)

Measured at 6 months and final assessment at one year.

Overall study start date
22/11/2011

Completion date
22/09/2016

Eligibility

Key inclusion criteria
1. Adults aged 70 years or older, either sex
2. Amnestic according to Consortium to Establish a Registry for Alzheimer's Disease (CERAD) cognitive battery norms
3. MiniMental State Examination (MMSE) score range between 24–30
4. Geriatric Depression Scale less than/equals 4/5
5. Clinical Dementia rating scale score of less than/equals 0.5
6. Participants should be nonsmoking, in good general health and English speaking in order to allow valid cognitive assessment to take place
7. Willing and able to participate in study

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Less than 70 years old
2. Recent change in relevant medication
3. Current or recent smoker.
4. With 8 teeth or less
5. Not deemed sufficiently fit to undergo operative dental treatment including extractions
6. Recent active periodontal treatment
7. Reporting a history of local oropharyngeal radiotherapy resulting in oral dryness

Date of first enrolment
22/11/2011

Date of final enrolment
22/11/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London (UK)

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Sponsor type

University/education

Website
http://www.kcl.ac.uk/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NIHR Biomedical Research Centres at South London and Maudsley NHS Foundation Trust (SLaM) and Guy's and St Thomas' NHS Foundation Trust (GST) with King's College London (KCL) (UK)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
12/03/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date