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A study to survey the oral health status of Canadian seniors and to prevent poor oral health in Canadian seniors

Submission date
11/08/2023

Recruitment status
No longer recruiting

Registration date
18/08/2023

Overall study status
Completed

Last Edited
01/09/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This is a study of (a) the oral health status of Canadian seniors and of (b) preventive interventions to improve the oral health of Canadian seniors. There is minimal data on the oral health of Canadian seniors and limited information about what might be done to improve oral health in this cohort.

Who can participate?
Individuals over 65 years of age will be recruited from the Ottawa community via newsletters and targeted mailing/phone calls. Long-term care residents will be recruited from the Bruyère Residence in St Louis.

What does the study involve?
The study has 2 parts:
Part A is a survey of oral health status and involves 1 study visit. Participants will answer questions about their oral health care and will undergo a dental examination by a registered hygienist that will document oral health status including the number of teeth, bleeding on probing sites, periodontal pockets and other variables. Participants in Part A who meet specific criteria will be invited to enrol in Part B.
Part B is a randomized, placebo-controlled, double-blinded, multi-site, prospective study of a specific medication's (Prevora) ability to treat chronic oral inflammation and arrest incipient lesions. Part B involves 5 study visits over 60 days. Prevora is a topical, high-strength, sustained-release, broad-spectrum antiseptic applied to the teeth and gum line of adults at high risk of poor oral health. Prevora is approved by Health Canada (DIN 02046245). In this seniors' study, Prevora will be applied using a rapid (5-7 minutes), non-invasive procedure which generates no aerosols. Four sessions will be scheduled for the drug application which will be done by a study hygienist or a study nurse. A final session will be scheduled for a dental hygienist examination that will repeat the process completed in Part A.

What are the possible benefits and risks of participating?
The possible benefits of participating include (a) a hygienist assessment of oral health (Part A);

(b) a reduced incidence of dental caries (Part B) and (b) reduced oral inflammation and associated reduction in periodontal disease (Part B). There are no known risks for related serious adverse events for the study medication. Related adverse events are a temporary sensation of a coating on the teeth, a short stinging of the oral mucosa and a short bitter taste. None of these side effects have prevented the patient from continuing with the Prevora treatment plan.

Where is the study run from?
CHX Technologies Inc (Canada)

When is the study starting and how long is it expected to run for?
June 2022 to September 2023

Who is funding the study?
CHX Technologies Inc (Canada)

Who is the main contact?
Heidi Sveistrup (Principal Investigator), HSveistrup@Bruyere.org
Andrea Pepe (Study coordinator), APepe@Bruyere.org

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A study to survey the oral health status of Canadian seniors and to prevent poor oral health in Canadian seniors

Study objectives
Phase A: Document oral health in a sample of up to 300 older adults living in the community (independent or assisted living) and long-term care
Phase B: Prevora will demonstrate a decrease in chronic oral inflammation (as defined by bleeding on probing sites) compared to sterile water

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/10/2022, Bruyère Research Ethics Board (43 Bruyère Street, Ottawa, K1N 5C8, Canada; +613-562-6262 ext 4003; REB@bruyere.org), ref: M16-22-052

Study design
Randomized placebo-controlled double-blinded multi-site prospective study with a prior cross-sectional cohort study

Primary study design
Interventional

Study type(s)
Screening, Treatment, Efficacy

Health condition(s) or problem(s) studied
Decrease in chronic oral inflammation in community living (independent and assisted living) older adults and older adults living in long-term care.

Interventions
Phase A: Residents of the greater Ottawa community, Bruyere Village and Bruyère long-term care will undergo an oral health examination by a registered dental hygienist. The examination will note the number of teeth, the number of decayed, missing and filled teeth, cavities, gum disease by stage, dental pain, visits to the dentist, oral hygiene behavior, medical conditions, medications that are taken, and basic demographic data.

Phase B: Of the individuals screened, those who meet the eligibility criteria will be invited to the randomized placebo-controlled trial. The participants will be split evenly between the 3 cohorts (independent living, assisted living, long-term care), and will be randomized equally into active and placebo arms. Participants will have 4 treatment applications over approximately 8 weeks and will be treated with Prevora or its placebo (sterile water). The application hygienist or nurse will apply the treatment with a small brush over the teeth and gumline of the participant in a short procedure that will take approximately 5-7 minutes. A final visit will be a dental reassessment conducted by the initial hygienist to note any changes in the primary and secondary oral health outcomes.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Prevora Stage 1, Prevora Stage 2 (DIN 02046245)

Primary outcome(s)
Change in the mean number of Bleeding on Probing (BOP) sites measured using a periodontal probe during an oral assessment at Screening and Visit 5, active versus control

Key secondary outcome(s))
1. Change in the mean number of periodontal pockets between 4 and 5mm, and greater than 5mm, measured using a periodontal probe between Screening and Visit 5, active versus control
2. Change in the mean number of incipient caries lesions identified by visual screening during an oral exam from Screening to Visit 5, active versus control
3. Differences in self-reported tolerance and acceptance to treatment measured using a visual-analogue-scale (VAS), active versus control at Visit 5
4. Differences in self-reported general well-being, as measured using a VAS, active versus control at Visit 5

Completion date

30/09/2023

Eligibility

Key inclusion criteria
Phase A:
1. Older adults (65 years of age and over at screening)
2. Residents of the Greater Ottawa community and Bruyère independent living, assisted living and longterm care

Phase B:
1. Matches the criteria of Phase A
2. Clears the dental screening performed in Phase A:
2.1. Bleeding on probing at ≥ 12 sites at Screening
2.2. Minimum of 15 natural teeth
2.3. Willing and able to provide informed consent
2.4. Able to complete the study as judged by the investigators
2.5. Fully vaccinated against COVID 19

Participant type(s)
Resident

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Sex
All

Total final enrolment
151

Key exclusion criteria
Phase B
1. Not 65 years of age or over
2. No bleeding on probing at 12 or more sites at Screening
3. Not having 15 natural teeth or more
4. Active caries which, in the judgement of the investigators, could require major surgical restoration and referral to a dentist. Those that can be readily managed by the examining hygienist (for example, small caries only requiring a temporary filling or silver diamine fluoride) will still be included in Part B.
5. Severe periodontal disease which, in the judgement of the investigators, could require surgery or a level of periodontal scaling such that participation in the study will be delayed
6. Undergoing periodontal care by a dentist or hygienist which in the judgement of the investigators could confound the study results.

7. Known allergies to the ingredients of the study medications (chlorhexidine, Sumatra benzoin, ethanol and polymethylmethacrylate)
8. Taking anti-inflammatory medication (excluding baby aspirin, prednisone or NSAIDS) or medications for periodontal conditions (e.g. Periostat, chlorhexidine rinse, PerioChip or Arestin).
9. At Screening, taking antibiotics for oral abscesses, oral pain or taking antibiotics for more than 14 days
10. Uncontrolled epilepsy
11. A gag reflex
12. Cancer that is in an active stage or has been treated with chemotherapy and/or radiation in the past year or in the next 12 months
13. Severe bleeding disorders (given the need to conduct debridement in this study)
14. Behavioral disorders which in the judgement of the investigators threaten the patient's tolerance to treatment and participation in the study
15. Involved in another drug trial
16. Unwilling or unable to provide informed consent including consent by the Substitute decision maker
17. An evident inability to complete the study as judged by the investigators
18. Not fully vaccinated against COVID 19

Date of first enrolment
15/11/2022

Date of final enrolment
13/06/2023

Locations

Countries of recruitment
Canada

Study participating centre
Bruyère
75 Bruyère St
Ottawa
Canada
K1N 5C7

Study participating centre
Good Companions Seniors' Centre
670 Albert St
Ottawa
Canada
K1R 6L2

Study participating centre

Bruyere Village
889 Hiawatha Park Road
Ottawa
Canada
K1C 3B1

Sponsor information

Organisation
CHX Technologies Inc

Funder(s)

Funder type
Industry

Funder Name
CHX Technologies Inc

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Heidi Sveistrup (HSveistrup@Bruyere.org).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Baseline results	07/08/2025	01/09/2025	Yes	No
Other files		09/08/2024	09/08/2024	No	No
Participant information sheet	Participant information sheet	14/09/2022	18/08/2023	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes