

The effect of improved oral prostheses on the nutritional state of elderly edentulous individuals

Submission date 20/10/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 28/07/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/10/2013	Condition category Oral Health	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

UCT-36052

Study information

Scientific Title

The effect of improved oral prostheses on the nutritional state of elderly edentulous individuals: a randomised controlled trial

Acronym

SIN II

Study objectives

Null Hypothesis:

That there will be no difference in nutritional status measured by serum homocysteine levels in elderly edentulous males and females wearing mandibular 2-implant overdentures and those wearing mandibular conventional dentures at six months following delivery of the prostheses.

Ethics approval required

Old ethics approval format

Ethics approval(s)

McGill University Faculty of Medicine IRB, original approval received November 15, 2002; renewed yearly; latest renewal approved 29 August 2006 (study number A08-M75-02B).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Edentulism (lack of all teeth)

Interventions

Control: Complete conventional dentures

Experimental: Mandibular 2-implant overdenture with ball attachments and maxillary conventional denture

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Serum level of homocysteine.

Key secondary outcome(s)

1. Patient satisfaction
2. Vitamin status

3. Changes in serum albumin
4. Changes in dietary habits
5. Changes in function
6. Cost effectiveness

Completion date

31/12/2006

Eligibility

Key inclusion criteria

1. Male and female seniors aged 65 and older
2. Completely edentulous for a minimum of five years
3. Wishing to replace existing conventional dentures
4. An adequate understanding of written and spoken English or French
5. Able to understand and respond to questionnaires used in the study
6. Willing and able to accept the protocol and give informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Insufficient bone to place two implants in the anterior mandible
2. Other oral conditions that preclude immediate prosthetic treatment
3. Acute or chronic symptoms of temporomandibular disorders
4. History of radiation therapy to the orofacial region
5. Systemic or neurological disease that contraindicate implant surgery
6. Any neoplasia diagnosed less than five years previously
7. Body mass index (BMI) less than 20 or greater than 32 kg/m²
8. Score of 20 or less on the Mini-Mental State Evaluation
9. Taking any of the following which will affect blood nutrient concentrations:
 - 9.1. Dietary supplements
 - 9.2. Anti-neoplastic medication
 - 9.3. Phenytoin or corticosteroids
 - 9.4. Insulin
10. Other conditions that jeopardise surgical treatment (e.g. alcoholism)
11. Psychological or psychiatric conditions that could influence diet and reaction to treatment

Date of first enrolment

01/09/2002

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Canada

Study participating centre

Oral Health and Society Research Unit

Montreal, Quebec

Canada

H3A 2A7

Sponsor information

Organisation

McGill University (Canada)

ROR

<https://ror.org/01pxwe438>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: UCT-36052)

Funder Name

Straumann Canada (Canada)

Results and Publications

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	etiological factor results	01/05/2008		Yes	No
Results article	sex differences results	01/05/2008		Yes	No
Results article	mandibular bone height results	01/11/2010		Yes	No
Results article	implant overdentures and nutrition results	01/01/2012		Yes	No
Results article	treatment satisfaction results	01/08/2012		Yes	No
Results article	dietary intake results	01/12/2013		Yes	No
Other publications	research approaches	01/12/2008		Yes	No
Other publications	methodological issues	01/04/2009		Yes	No