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Clinical wear and incidence of temporomandibular disorders among complete denture patients

Submission date 21/02/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/03/2016	**Overall study status** Completed	
Last Edited 04/03/2016	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
False teeth (dentures) are mainly made from two types of material: acrylic resin and porcelain. Wearing complete dentures may cause temporomandibular disorder (TMD). TMD is a problem affecting the chewing muscles and the joints between the jaw and the skull, which can cause pain and difficulties eating. This study aims to assess the role of clinical wear in the incidence of TMD among patients with acrylic resin and porcelain complete dentures.

Who can participate?
Patients requiring complete dentures.

What does the study involve?
Participants are randomly allocated into two groups. One group receives upper and lower complete dentures with teeth made of acrylic resin. The other group receives upper and lower complete dentures with teeth made of porcelain. Both groups are followed up after 6, 12, 18 and 24 months for assessment of clinical wear and incidence of TMD.

What are the possible benefits and risks of participating?
Participants will benefit from receiving dentures and continuous clinical follow up. The results of the study will improve our knowledge of the causes of TMD and provide a basis for developing a new artificial teeth material.

Where is the study run from?
University of Khartoum (Sudan)

When is the study starting and how long is it expected to run for?
January 2014 to January 2016

Who is funding the study?
Albaha University (Saudi Arabia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Effect of clinical wear in incidence of temporomandibular disorders among complete denture patients: a randomized clinical trial

Study objectives
Clinical wear of denture teeth is usually expected in patients after years of denture use. Posterior teeth seemed to be more affected by food abrasion. Development of facets in the anterior teeth due to attrition (tooth to tooth contact) usually occurs. A positive relationship has been found between the duration of complete denture wearing and the incidence of temporomandibular disorder (TMD).

The aim of this study is to determine the effects of clinical wear on the incidence of temporomandibular disorders among complete denture patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Technical and ethical committee at University of Khartoum, 01/01/2014

Study design
Randomized clinical trial, parallel arm design

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Temporomandibular disorder

Interventions
The patients who agreed to participate in this study were assigned randomly using random table numbers into two groups:
Group 1 (intervention group) patients received upper and lower complete dentures with teeth made of heat cure acrylic resin (Meliodent- Bayer dental, Germany batch no 54105L-2).
Group 2 (control group) patients received upper and lower complete dentures with teeth made of porcelain (dent supply, Germany batch no 43105L-1).

The patients were followed up for two years at 6, 12, 18 and 24 months for assessment of clinical wear and incidence of TMD.

Intervention Type
Procedure/Surgery

Primary outcome measure
Clinical wear measured using computerized imaging measuring system at 6, 12, 18 and 24 months

Secondary outcome measures
Incidence of TMD measured using Helkimo clinical dysfunction index at 6, 12, 18 and 24 months

Overall study start date
01/01/2014

Completion date
05/01/2016

Eligibility

Key inclusion criteria
Edentulous patients in need of complete dentures

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
64

Key exclusion criteria
1. Patients with severe malocclusion
2. Patients with systematic diseases affecting the temporomandibular joint like generalized fibromyaligia, rheumatoid arthritis or post-traumatic stress disorder

Date of first enrolment
15/01/2014

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
Sudan

Study participating centre
Faculty of Dentistry, University of Khartoum
Khartoum
Sudan
00249

Sponsor information

Organisation
Albaha University (Saudi Arabia)

Sponsor details
Al-Baha
Al-Baha
Saudi Arabia
00966

Sponsor type
Government

ROR
https://ror.org/0403jak37

Funder(s)

Funder type
University/education

Funder Name
Albaha University (Saudi Arabia)

Results and Publications

Publication and dissemination plan
The study is currently under process of publication in one of the dentistry international journals. It will include results and main findings from this study. The published article will be announced for all dentistry specialist and students.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request