ISRCTN71924789 https://doi.org/10.1186/ISRCTN71924789

Nutraceutical-based therapy in the management of disorders of the jaw joint and muscles that control jaw movement

Submission date
31/10/2023

Recruitment status
No longer recruiting

Registration date
08/12/2023

Overall study status
Completed

Last Edited
08/07/2024

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Temporomandibular disorders (TMDs) are a subgroup of craniofacial pain disorders, involving pain and dysfunction of the temporomandibular joint (TMJ), masticatory muscles and associated musculoskeletal structures of the head and neck. This study aims to evaluate the effects of short-term treatments with nutraceuticals in subjects with TMDs focusing on the improvement of quality of life in terms of the reduction of painful TMD symptoms, sleep and psychological outcomes.

Who can participate?
Patients with TMDs aged between 18 and 75 years old

What does the study involve?
The nutraceutical used is composed of Boswellia Serrata Casperome, Magnesium, Tryptophan and vitamins B2 and D with a posology of 1 tablet per day before sleep for 40 days.

Subjects with neuromuscular disorders in the temporomandibular region are eligible for the study and randomly divided into 2 groups (treatment group and control group). The presence of muscle pain, headache, neck pain and sleep/emotional disorders will be assessed at T0 (baseline) and at T1 (after treatment/40 days). The treatments with nutraceuticals and their respective controls will be compared with respect to painful symptomatology. Further tests will be performed to assess differences in sleep/emotional disorders between groups.

What are the possible benefits and risks of participating?
A reduction in muscle tension is expected, which also has a beneficial effect on sleep quality. No adverse effects are expected. The possibility of no effect may be contemplated.

Where is the study run from?
Department of Oral and Maxillo-facial Sciences, Sapienza University of Rome (Italy)

When is the study starting and how long is it expected to run for?
February 2018 to 20 June 2023

Who is funding the study?
Sapienza University of Rome (Italy)

Who is the main contact?
Paola di Giacomo, p.digiacomo@uniroma1.it (Italy)

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Paola Di Giacomo

ORCID ID
https://orcid.org/0000-0002-5657-1684

Contact details
Via Caserta 6
Rome
Italy
00161
None provided
p.digiacomo@uniroma1.it

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Nutraceutical-based therapy in the management of temporomandibular disorders

Acronym
NTTMD

Study objectives

Can a broad-spectrum nutraceutical treatment be considered as effective as short-term therapy for temporomandibular disorders (TMDs)?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/05/2018, Department of Oral and Maxillo-facial Sciences, Sapienza university of Rome (Via Caserta 6, Rome, 00161, Italy; +39 0649976611; dip.odonto@cert.uniroma1.it), ref: 0000698

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied
Temporomandibular joint disorders

Interventions
This study investigates whether a broad-spectrum nutraceutical treatment is as effective as short-term therapy for temporomandibular disorders (TMDs).
Computer-generated randomization will be undertaken with a random allocation sequence and a block size of 2. Specifically, in the case that no orthopedic treatment has yet started, patients will be enrolled in: Treatment with Nutraceutical (Nutraceutical group – Group I); No treatment (Control Group Ia). In case of ongoing occlusal splint therapy, patients will be enrolled in: Treatment with Neutraceutical and splint therapy (Neutraceutical + Splint Group – Group II); Treatment with occlusal splint only (Control Group IIa).

The participants are blinded to group assignments. Participants will be told that they have an equal chance of being assigned to one of the two arms. After the recruitment phase, subjects assigned to Groups I and II will take one tablet of the supplement per day before sleep for 40 days. The administered nutraceutical was based on Magnesium, Tryptophane, Boswellia Serrata Casperome®, and Vitamins B2, D, and PP.

Intervention Type
Supplement

Primary outcome(s)
Intensity of temporomandibular disorder pain measured using the Verbal Numerical Scale (VNS) at T0 (before treatment) and T1 (after treatment)

Key secondary outcome(s))
1. Improvement of quality of life relating to physical disabilities measured using the Verbal-Numerical Scale (VNS) to report the severity, if present, of comorbidities, such as headache and neck pain and presence/absence of sleep/emotional disturbances (only with a dichotomic

classification yes/no) at T0 and T1
2. Analysis of mandibular function (presence of articular noises, evaluation of functional excursions and maximum mouth opening) and palpatory examination were also recorded at T0 and T1

Completion date
20/06/2023

Eligibility

Key inclusion criteria
1. Presence of dysfunctions of the craniocervical musculature, in the presence or absence of parafunction
2. Presence of muscular pain at the level of the masseter of the medium-high entity with a minimum value of 40 and a maximum of 100 according to the VNS (verbal numerical scale), spontaneous and/or investigated by palpatory manoeuvres
3. Presence of arthralgia in at least one temporomandibular joint
4. Presence of the following comorbidities such as headache attributed to temporomandibular disorders, cervicalgia
5. Presence of sleep disturbances (no OSAS) and emotional factors (stress and anxiety) investigated with a nominal scale (presence or absence)
6. Patients waiting for or undergoing conservative gnathological therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Total final enrolment
193

Key exclusion criteria
1. Psychiatric pathologies
2. Systemic pathologies with disease-related muscular impairment
3. Pain therapy or myorelaxant medication

Date of first enrolment

01/01/2021

Date of final enrolment
01/01/2022

Locations

Countries of recruitment
Italy

Study participating centre
Department of Oral and Maxillo-facial Sciences
Sapienza University of Rome
Via Caserta 6
Rome
Italy
00161

Sponsor information

Organisation
Sapienza University of Rome

ROR
https://ror.org/02be6w209

Funder(s)

Funder type
University/education

Funder Name
Sapienza Università di Roma

Alternative Name(s)
Sapienza University of Rome, Università degli Studi di Roma "La Sapienza”, Sapienza-Università di Roma, Sapienza, Uniroma1

Funding Body Type
Government organisation

Funding Body Subtype

Universities (academic only)

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Paola di Giacomo, p.digiacomo@uniroma1.it.

All consent will be requested and obtained from each participant before participating in the study. Anonymous (without any sensible data) database with each collected data will be available for 5 years.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/07/2024	08/07/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes