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Syalogram in chronic fatigue syndrome

Submission date	Recruitment status	[X] Prospectively registered
09/04/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/04/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/04/2009	Musculoskeletal Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.institutferran.org/investigacion.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
218/09

Study information

Scientific Title
The syalogram: utility of a biochemical test for evaluation of salival alterations in chronic fatigue syndrome (CFS) and other related diseases

Acronym
Syalogram in CFS

Study objectives
In chronic fatigue syndrome (CFS) salivary disorders are common. Xerostomia, burning mouth, gingivitis and mucosal ulcers are clinical presentations of salivary disorders.

Hypothesis:
We have developed an easy biochemical salivary test to determine pH, sodium (Na), potassium (K), proteins and cortisol concentrations, and the volume/minute of salivary secretion: the syalogram. We want to standardise it as a reliable method of testing salivary function. We want to find the alterations of the salivary function in patients with chronic fatigue syndrome (CFS) /myalgic encephalomyelitis (ME), fibromyalgia (FM), Sjögren's syndrome and other related diseases.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Center for Applied Medical Research (CIMA) Clinic committee gave approval (ref: 23/2009)

Study design
Interventional non-randomised non-controlled clinical descriptive study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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
Chronic fatigue syndrome/fibromyalgia/Sjögren's syndrome

Interventions

Collection of one sample of saliva for biochemical test and one sample for volume/minute determination. There is no follow-up and the duration of each test is under one minute.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Concentration of Na, K, cortisol, proteins, pH.

Secondary outcome measures
Volume/minute of saliva secreted.

Overall study start date
01/05/2009

Completion date
30/08/2011

Eligibility

Key inclusion criteria
1. Chronic fatigue syndrome (CFS), fibromyalgia (FM), Sjögren's syndrome or sicca syndrome
2. One of the following symptoms: xerostomia, burning mouth, mucosal ulcers
3. No age range, either sex

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
50

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/05/2009

Date of final enrolment
30/08/2011

Locations

Countries of recruitment
Spain

Study participating centre
Paseo Manuel Girona, 23
Barcelona
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Sponsor information

Organisation
Foundation for Fibromyalgia and Chronic Fatigue Syndrome (Spain)

Sponsor details
Paseo Manuel Girona, 23
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Sponsor type
Research organisation

Website
http://www.fundacionfatiga.org

ROR
https://ror.org/03p4nrj93

Funder(s)

Funder type
Research organisation

Funder Name
Foundation for Fibromyalgia and Chronic Fatigue Syndrome (Fundacion para la Fibromialgia y el Síndrome de Fatiga Crónica) (Spain)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration