

Syalogram in chronic fatigue syndrome

Submission date 09/04/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/04/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

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Contact details

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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

Spain

08034

Sponsor information

Organisation

Foundation for Fibromyalgia and Chronic Fatigue Syndrome (Spain)

Sponsor details

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info@fundacionfatiga.org

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