

Syalogram in chronic fatigue syndrome

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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 sialogram. 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)

Primary study design

Interventional

Study design

Interventional non-randomised non-controlled clinical descriptive study

Study type(s)

Screening

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(s)

Concentration of Na, K, cortisol, proteins, pH.

Key secondary outcome(s)

Volume/minute of saliva secreted.

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

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

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes