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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

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 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

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
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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