

Videofluoroscopic evaluation of the therapeutic effect of Tabasco® sauce in dysphagic patients

Submission date 20/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/11/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/11/2010	Condition category Signs and Symptoms	<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

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CAPS-01

Study information

Scientific Title

Videofluoroscopic evaluation of the therapeutic effect of Tabasco® sauce in dysphagic patients:
An open-label, non-randomised controlled trial

Study objectives

Background:

Oropharyngeal dysphagia is the difficulty to form or to move the alimentary bolus from the mouth to the oesophagus. It is a highly prevalent symptom in neurological and older patients and causes malnutrition and aspiration pneumonia. There are no pharmacological strategies for dysphagic patients and most are treated by changes in bolus viscosity.

Hypothesis:

Capsaicin from Tabasco sauce acts on the oropharyngeal transient receptor potential cation channel (TRPV1), increasing sensory input and the release of substance P. These actions may accelerate the oropharyngeal swallow response, improving the swallowing in dysphagic patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The local ethics committee (Comitè Ètic d'Invstigació Clínica de l'Hospital de Mataró, Consorci Sanitari del Maresme) approved on the 24th of September 2008

Study design

Single centre open label non-randomised controlled trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please contact Dr Pere Clavé [pclave@teleline.es] to request a patient information sheet

Health condition(s) or problem(s) studied

Oropharyngeal dysphagia

Interventions

All participants will undergo a clinical study of swallowing by a questionnaire and clinical examination by the volume-viscosity swallow test (V-VST)

Dysphagic patients will be randomised to either the experimental or control group. Healthy volunteers will enter the control group.

1. Control group:

1.1. Videofluoroscopic control study during bolus swallow of 5, 10 and 20 mL of control substance, to describe biomechanical abnormalities (videofluoroscopic signs) that lead to the pathophysiology of dysphagia in each patient

2. Experimental group:

2.1. Oropharyngeal sensitization by swallowing nectar bolus of 5 mL supplemented with capsaicin

2.2. Two videofluoroscopic studies during bolus intake of 5, 10 and 20 mL of experimental substance

2.3. Determination of the degree of acceptability of the experimental substance and comparison with the control substance by hedonic scale

All participants will be monitored for adverse effects by a phone call within 48 hours of the study.

Intervention Type

Other

Phase

Phase IV

Primary outcome measure

1. Efficacy signs:

1.1. Lip closure

1.2. Capacity to form the bolus

1.3. Tongue propulsion

1.4. Presence of oral and pharyngeal residue

1.5. Impaired upper oesophageal sphincter opening

2. Safety signs:

2.1. Glosopalatal seal

2.2. Laryngeal vestibule closure

2.3. Local cords closure

3. Timing of oropharyngeal swallow response: Timing of opening and closing of

3.1. Glosopalatal junction

3.2. Velopharyngeal junction

3.3. Laryngeal vestibule

3.4. Upper oesophageal sphincter

Secondary outcome measures

1. Hyoid movement:

1.1. Maximal vertical and anterior extension

1.2. General profile

2. Mechanics and kinematics:

2.1. Bolus propulsion force

2.2. Mean and maximal bolus velocity

2.3. Kinetic energy

Overall study start date

25/09/2008

Completion date

14/07/2010

Eligibility

Key inclusion criteria

1. Age >18
2. History of swallowing difficulties associated with aging and/or neurological diseases (neurodegenerative or non-progressive neurological diseases)
3. Study explained and written subject information given
4. Informed consent signed

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

8 healthy volunteers; 33 dysphagic patients with Tabasco treatment; 33 dysphagic patients with thickener treatment

Key exclusion criteria

1. Patients suffering idiosyncratic phenomena or who are allergic to any medication, especially iodinated contrast media
2. Patients suffering major respiratory disease or undergoing any type of surgery in the three months prior to the study
3. Patients with a background of alcohol dependence or other drug dependence
4. Currently participating or having participated in another clinical trial during the last 4 weeks prior to the beginning of the study

Date of first enrolment

25/09/2008

Date of final enrolment

14/07/2010

Locations

Countries of recruitment

Spain

Study participating centre
Hospital de Mataró
Mataró
Spain
08304

Sponsor information

Organisation
Hospital de Mataró (Spain)

Sponsor details
c/o Pere Clavé
Carretera Cirera s/n
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08304

Sponsor type
Hospital/treatment centre

ROR
<https://ror.org/04cy4z909>

Funder(s)

Funder type
University/education

Funder Name
Ministry of Science and Innovation (Ministerio de Ciencia e Innovación) (Spain) - Collegial Scholarship 2009/2010, Official Pharmaceutical College of Barcelona FIS Project (ref: PS09/01012) (Beca Collegial 2009/2010, Collegi Oficial de Farmacèutics de Barcelona)

Funder Name
Proyecto FIS)

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