ISRCTN31088564 https://doi.org/10.1186/ISRCTN31088564

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

Submission date 20/10/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/11/2010	**Overall study status** Completed	
Last Edited 25/11/2010	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Pere Clavé

Contact details
Hospital de Mataró
Carretera Cirera s/n
Planta -2 porta 64
Mataró
Spain
08304

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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 videofluroscopic 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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

ROR
https://ror.org/04cy4z909

Funder(s)

Funder type
University/education

Funder Name
Ministry of Science and Innovation (Ministerio de Ciencia e Inovación) (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration