ISRCTN13966417 https://doi.org/10.1186/ISRCTN13966417

Comparison of the incidence of facial nerve dysfunction in patients submitted to surgery for parotid gland tumors with or without facial nerve monitoring with continuous electromyographic register during the surgery

Submission date	Recruitment status	[_] Prospectively registered
04/02/2018	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
01/03/2018	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
12/12/2019	Surgery	

Plain English summary of protocol

Background and study aims
The parotid gland is situated in the mouth and makes saliva. Lumps can occur in this gland due to abnormal growth, and are called parotid gland tumours. They can be removed by surgery called superficial parotidectomy. Temporary facial nerve weakness (dysfunction) is the most common complication following this surgery, caused by damage to an important nerve that passes through the parotid gland, called the facial nerve.
A series of techniques called continuous intraoperative electromyography can be used to monitor the electrical activity of the facial nerve in an attempt to reduce the incidence of this complication.
The objective of this study is to prospectively evaluate adult patients with benign parotid tumors that will be treated with superficial parotidectomy with or without facial nerve monitoring, and compare the rates and degree of immediate facial nerve dysfunction between these groups and evaluate specific patient outcome results related to these facial disabilities. This study aims to see if facial nerve monitoring reduces the rate and degree of facial nerve dysfunction following facial surgery to remove parotid tumours.

Who can participate?
Adults aged 18 to 85 years with benign parotid tumours

What does the study involve?
Participants are randomly allocated to the intervention group or control group.
Those in the intervention group undergo superficial parotidectomy with continuous facial nerve monitoring using intraoperative electromyography. Those in the control group have the surgery with standard visual facial nerve monitoring.
Participants have their facial movements filmed prior to surgery and at 7, 30, 90 and 180 days after the procedure.

What are the possible benefits and risks of participating?
Participants may benefit from the reduced risk of face paralysis during surgery and also help others benefit from this in the future if monitoring is shown to be successful.
There are no additional risks for participants, other than those already related to this type of surgery, such as pain and discomfort in the operated area, temporary or permanent facial paralysis and facial hematoma (bleeding under the skin of the face).

Where is the study run from?
1. Hospital das Clínicas da Universidade Estadual de Campinas (Brazil)
2. Hospital São José Joinville (Brazil)

When is the study starting and how long is it expected to run for?
April 2015 to June 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Agnaldo Jose Graciano (Scientific)
agnaldograciano@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Agnaldo Graciano

ORCID ID
http://orcid.org/0000-0003-4643-929X

Contact details
Faculty of Medical Sciences
State University of Campinas
Rua Tessália Vieira de Camargo 126
Cidade Universitária
Campinas
Brazil
13083-887
+55 47 3422 8262
agnaldograciano@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CAAE: 27574914.4.2094.5404

Study information

Scientific Title
Facial Nerve Monitoring during superficial parotidectomy for benign tumors of the parotid gland: a prospective randomized trial

Study objectives
Facial nerve monitoring may reduce the incidence of facial nerve dysfunction and/or it's degree following superficial parotidectomy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Faculty of Medical Sciences State University of Campinas, 09/04/2015, ref: 1008.206

Study design
Two center prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Facial nerve dysfunction following superficial parotidectomy

Interventions
Participants with benign tumours of the parotid gland undergoing superficial parotidectomy are randomly assigned to the intervention (facial nerve monitoring) or control group on the day of surgery, using a randomized list created by random allocation software.
The intervention group undergo surgery with facial nerve monitoring using continuous intraoperative electromyography, which registers any stimulus that could indicate an irritation of the facial nerve.
The control group undergo standard surgery with continuous visual monitoring of the facial

nerve, but no additional information from the electromyographic register.
Post operative facial nerve movement will be recorded using a HD camera and graded by experienced physicians at 30, 90 and 180 days after the surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
Incidence of facial nerve dysfunction measured by experienced physicians up to 30 days (immediate) and 180 days (late) following superficial parotidectomy

Secondary outcome measures
Degree of facial nerve dysfunction evaluated by experienced physicians at 30, 90 and 180 days following surgery

Overall study start date
15/01/2015

Completion date
15/09/2018

Eligibility

Key inclusion criteria
1. Adult
2. Aged 18 to 85 years
3. Benign parotid tumor(s)
4. Normal neuromuscular facial function prior to surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Total final enrolment
124

Key exclusion criteria
1. Malignant parotid tumor(s)

Date of first enrolment
15/04/2015

Date of final enrolment
15/06/2018

Locations

Countries of recruitment
Brazil

Study participating centre
Hospital das Clínicas da Universidade Estadual de Campinas
Campinas
Brazil
13083-888

Study participating centre
Hospital São José Joinville
Joinville
Brazil
89202-000

Sponsor information

Organisation
Faculty of Medical Sciences - UNICAMP

Sponsor details
Rua Tessália Vieira de Camargo
126 - Cidade Universitária Zeferino Vaz.
Campinas
Brazil
13083-887

Sponsor type
University/education

ROR
https://ror.org/04wffgt70

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
We plan to publish the results of this trial in a peer reviewed medical periodical.

Intention to publish date
15/11/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Agnaldo Graciano at agnaldograciano@gmail.com. Individual participant data that underlie the results reported in this article, including text, tables, figures, appendices and study protocol will be available for researchers that provide a proposal for individual participant data meta-analysis. Beginning 3 months ending 3 years after publication.

Additional and raw data can be accessed at: http://repositorio.unicamp.br/handle/REPOSIP/332793 (added 12/12/2019)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2018		Yes	No