TachoSil patch application as replacement of closed suction wound drainage by parotid gland surgery; a prospective study

Published: 06-05-2014
Last updated: 20-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON39715

Source
ToetsingOnline

Brief title
TachoSil parotidectomy

Condition

- Miscellaneous and site unspecified neoplasms benign
- Vascular therapeutic procedures

Synonym
parotid surgery, surgical wound problems, wound complications

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Takeda,Takeda Nederland B.V.

Intervention

Keyword: closed suction drainage, complications, Parotid gland surgery, Sealing patch

Outcome measures

Primary outcome

The outcome of efficacy is measured by the derivative outcome of wound

complications like haematoma, haemorrhage, wound infection, seroma, dehiscence,

skin necrosis.

Secondary outcome

Secondary parameters include facial nerve function and more tardy complications

like fistula, sialocele and Frey*s syndrome. Additionally, patient satisfaction

(measured by short survey), duration of hospital admission and the need for

re-admission will be recorded.

Study description

Background summary

Parotid gland surgery is the designated treatment for a tumor of the parotid gland, whether benign or malignant. The extent of the procedure is based on localization and histology. Most common a superficial parotidectomy is performed. Deep gland or malignant tumors require a more extensive procedure, involving the removal of the total gland, potentially combined with dissection of the lymph nodes of the neck. Risk of facial nerve dysfunction depends mainly on the dimension of chosen surgery, other complications are more widely seen in all types of parotidectomy. Those range from wound complication - including haematoma, haemorrhage, infection, dehiscence and necrosis - till complications resulting from anatomical changes like sialoceles or fistulas, Frey*s syndrome and from greater auricular nerve (GAN) dissection. In order to keep

postoperative fluid collections of blood, lymph and saliva restricted to a minimum in the surgical area, current common practice dictates the insertion of a closed suction drain (CSD) before closure.

Study objective

The primary objective of the study is to provide evidence that the use of a sealing surgical patch applied to the surgical field following parotidectomy is non-inferior in efficacy to the common practice of CSD insertion by wound closure, measured by post-operative wound complications. If so, TachoSil will be able to replace CSD because it is much more convenient for patients than a CSD. It means no irritation of the drain, no potential infection route and no need for specialized care in the hospital so more early discharge and resulting in recovery in the own home environment.

Study design

Patients undergoing parotid gland surgery and participating in this study will undergo the standard parotid surgery intended for their tumor, including the additional application of TachoSil to the surgical field. After this application no CSD will be placed. This will enable to perform the surgery under day care/short stay conditions. Postoperatively, the amount of complications will be recorded prospectively, together with the duration of hospital admission and the eventual need for re-admission.

Intervention

Application of TachoSil to the wound, after which no CSD will be placed.

Study burden and risks

Potential disadvantage for the patient is the risk of hypersensitivity reactions in case of allergy for human blood products or horse protein. Patients will be asked for a history of allergy, especially related to these products. A possible reaction is expected to occur within minutes till hours after surgery. At this moment, patients will be still in hospital so could directly receive specialized medical care conform current medical guidelines for allergy or shock.
Ultimately, this could result in opening of the wound and removal of TachoSil in case of a life threatening reaction.
Other problems could result out of the lack of CSD by not well-applied or well-functioning TachoSil. Leaking blood, lymph and/or saliva could form a fluid collection. Large collections will dictated the need of puncture by needle or even opening the wound and placing an CSD.
The application of TachoSil itself during surgery wil form no extra burden for participants.

Yet, participants will enjoy the expected benefits of the lack of wound drain and the use of TachoSil:
• No drain; this means no inconvenience of this drain and no possibility of infection through the drain.
• Day surgery; same day hospital admission and discharge so recovery in patients own environment.
• Significantly lower healthcare costs as result of shorter hospital admission.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients undergoing surgery for a parotid gland tumor.
• Indications for parotidectomy are
- fine needle aspiration cytology (FNAC) proven benign or malignant parotid tumors

- Persistent clinical suspicion of a parotid tumor despite negative FNAC.
• For this prospective study patients undergoing all forms of parotid surgery are eligible, when treatment with sole parotidectomy will be sufficient (i.e. no extensive surgery or adjuvant radiotherapy).
• Patients older than 18 years, there is no upper age limit.
• Signed informed consent is required.

Exclusion criteria

Patients meeting (one of) the following criteria are excluded from participation in this study:
• Pre-existing coagulation disorders (anticoagulant therapy must be on pause, continuing use of acetylsalicylic acid is permitted)
• History of surgery, radiation or open trauma to the ipsilateral neck or parotid area
• Receiving concurrent neck dissection because of the extent of the surgical field
• Known necessity of adjuvant radiotherapy (e.g. in case of malignancy of tumor spill).
• Known allergy for the product of TachoSil or its substances like for human blood products or horse protein.
• Known immunodeficiency, because of increased risk by transmitted viral agents.
• Anamnestic presence of pregnancy or nursery giving.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	75
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	TachoSil
Generic name:	TachoSil
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	06-05-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	25-08-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2012-005653-22-NL
CCMO	NL42707.031.14