Clinical trial results:
Use of TachoSil® for the prevention of postoperative complications after groin dissection in vulva cancer patients

Summary

EudraCT number	2016-001191-30
Trial protocol	DK
Global end of trial date	09 May 2022

Results information

Result version number	v1 (current)
This version publication date	16 December 2024
First version publication date	16 December 2024
Summary attachment (see zip file)	Abstract: USE OF TACHOSIL® FOR THE PREVENTION OF POSTOPERATIVE COMPLICATIONS AFTER GROIN DISSECTION IN VULVA CANCER PATIENTS (Abstract_Tacho_01032024.docx)

Trial information

Trial identification

Sponsor protocol code	IISR-2015-101127

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Copenhagen University Hospital
Sponsor organisation address	Blegdamsvej 9, Rigshospitalet, Denmark, 2100
Public contact	Ligita Paskeviciute Frøding, Department of Obstetrics & Gynecology, Copenhagen University Hospital, Rigshospitalet, Denmark, 0045 35459719, ligitapask@dadlnet.dk
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Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	02 September 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 May 2022
Global end of trial reached?	Yes
Global end of trial date	09 May 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate and compare the incidence of symptomatic lymphocele (defined by CTCAE 4.03 grade ≥2) within 4 weeks after surgery in women undergoing ILND for vulva cancer with or without the application of TachoSil® during surgery

Protection of trial subjects:

Non

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 74
Worldwide total number of subjects	74
EEA total number of subjects	74

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	26
From 65 to 84 years	46
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Patients with vulva cancer and inguinal lymphadenectomy were recrouted in to gynecologic oncology departments at Copenhagen University Hospital and Aarhus University Hospital

Pre-assignment

Screening details:

101 patients were screened for the inclusion. 74 patients were included and 27 were excluded due to exclusion criteria.

Period 1

Period 1 title	Intervention (Overall period) (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention

Arm description:

Patiens after inguinafemoral lymphadenectomy who were applied Tachosil prior standard wound closure

Arm type	Experimental
Investigational medicinal product name	Tachosil
Investigational medicinal product code	
Other name	Tachosil
Pharmaceutical forms	Sealant
Routes of administration	Use in body cavities

Dosage and administration details:

One patch per inguen

Arm title	Control

Arm description:

Patients after inguinofemoral lymphadenectomy, standard closure

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Intervention	Control
Started	39	35
Completed	39	35

Baseline characteristics

Reporting groups	
Reporting group title	Intervention
Reporting group description:	
Patiens after inguinafemoral lymphadenectomy who were applied Tachosil prior standard wound closure	
Reporting group title	Control
Reporting group description:	
Patients after inguinofemoral lymphadenectomy, standard closure	

Reporting group values	Intervention	Control	Total
Number of subjects	39	35	74
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	13	13	26
From 65-84 years	26	22	48
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	39	35	74

End points

End points reporting groups

Reporting group title	Intervention
Reporting group description:	
Patiens after inguinafemoral lymphadenectomy who were applied Tachosil prior standard wound closure	
Reporting group title	Control
Reporting group description:	
Patients after inguinofemoral lymphadenectomy, standard closure	

Primary: The primary outcome is the incidence of symptomatic lymphocele (defined by CTCAE 4.03 grade ≥2) within 4 weeks after surgery in women undergoing IL for vulva cancer with or without the application of TachoSil® during surgery.

End point title	The primary outcome is the incidence of symptomatic lymphocele (defined by CTCAE 4.03 grade ≥2) within 4 weeks after surgery in women undergoing IL for vulva cancer with or without the application of TachoSil® during surgery.
End point description:	
End point type	Primary
End point timeframe:	
4 weeks after surgery	

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	35		
Units: 1-4				
number (not applicable)				
Incidens of lymphocele	18	11		

Statistical analyses

Statistical analysis title	Descriptive statistics
Comparison groups	Control v Intervention
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.24
Method	Chi-squared

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

During one year post-surgery. Wound complications after groin dissection (lymphocele (6-40%), wound breakdown (13-39%) and cellulitis (14-57%)) are common surgical complications after lymphnode dissection in groins and were not considered as AEs or ARs.

Adverse event reporting additional description:

The clinical assesment was used. Events were considered to be possibly related to the TachoSil® if they occured in the time interval from the time of application of the patches and up to 24 hours after application. Adverse reactions occurring more than 24 hours after application were not be registered.

Assessment type	Systematic

Dictionary used

Dictionary name	None
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Events were considered to be possibly related to the TachoSil® if they occured in the time interval from the time of application of the patches and up to 24 hours after application. Adverse reactions occurring more than 24 hours after application were not registered. Wound complications after groin dissection (lymphocele (6-40%), wound breakdown (13-39%) and cellulitis (14-57%)) are common surgical complications after lymphnode dissection in groins and were not considered as AEs or ARs.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
02 March 2020	COVID-19 pandemic	-

Notes:

Limitations and caveats

None reported