Clinical trial results:
Adjuvante Imiquimod Therapie zur Senkung der Rezidivrate nach operativer Therapie bei analen HPV-Läsionen

Summary

EudraCT number	2017-000842-23
Trial protocol	AT
Global end of trial date	29 January 2021

Results information

Result version number	v1 (current)
This version publication date	27 March 2021
First version publication date	27 March 2021

Trial information

Trial identification

Sponsor protocol code	AdAM_2017

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Innsbruck
Sponsor organisation address	Anichstraße 35, Innsbruck, Austria, 6020
Public contact	Dr. med. Sascha Czipin, Medical University Innsbruck, ++43 51250480823, mui-sponsor@i-med.ac.at
Scientific contact	Dr. med. Sascha Czipin, Medical University Innsbruck, ++43 51250480823, mui-sponsor@i-med.ac.at

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	29 January 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 January 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary objective of the study is to evaluate the efficacy of combination therapy of surgical intervention and "adjuvant" topical Imiquimod therapy

Protection of trial subjects:

Since the recruitment phase never started, no patients have been enrolled. Hence no protection of trial subjects has been necessary

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No patients were recruited for this trial. "99999" is a value for 0 participants

Pre-assignment

Screening details:

N/A

Period 1

Period 1 title	Treatment period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Arm title	Imiquimod – Aldara 5%-Creme

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Imiquimod – Aldara 5%-Creme
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

Subject would have been treated using the following scheme: Each crucible contains 12.5 mg Imiquimod in 250 mg Creme (5%). The cream should be administered 3 times per week over a period of 12 weeks before going to bed. The creme should be left on the skin for 6 to 10 hours and can be washed away with water on the next morning.

Number of subjects in period 1	Imiquimod – Aldara 5%-Creme
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	Treatment period (overall period)

Reporting group description: -

Reporting group values	Treatment period (overall period)	Total	
Number of subjects	99999	99999	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Imiquimod – Aldara 5%-Creme

Reporting group description: -

Primary: Effectiveness of the Combination therapy of surgical therapy and "adjuvant" topical imiquimod therapy

End point title	Effectiveness of the Combination therapy of surgical therapy and "adjuvant" topical imiquimod therapy[1]

End point description:

End point type	Primary

End point timeframe:

N/A

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No subjects were included in this trial, therefore no statistical analysis was done.

End point values	Imiquimod – Aldara 5%-Creme			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: N/A	99999			

Notes:

[2] - "99999" is a value for 0 participants

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
01.07.2018 - 29.01.2021	
Adverse event reporting additional description:	
No patients were included in this trial, therefore no AEs and SAEs were reported	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.03

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: No subjects were included in this trial, therefore no AEs or SAEs were observed

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? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No subjects were enrolled in this trial. "99999" is a value for 0 participants, as it was not possible to fill in "0" for the number for included patients.

Notes: