



Clinical trial results:

Prospective Randomized Clinical Trial of Total Thyroidectomy (Tx) versus Thionamides (Anti-Thyroid Drugs) in Patients with Moderate-to-Severe Graves' Ophthalmopathy - a 1-year Follow-up

Summary

EudraCT number	2015-003515-38
Trial protocol	AT
Global end of trial date	17 November 2022

Results information

Result version number	v1 (current)
This version publication date	28 March 2023
First version publication date	28 March 2023

Trial information

Trial identification

Sponsor protocol code	GO-TXATD
-----------------------	----------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Vienna
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Dr. Lindsay Hargitai, Medical University Vienna, 43 14040056210, lindsay.hargitai@meduniwien.ac.at
Scientific contact	Dr. Lindsay Hargitai, Medical University Vienna, 43 14040056210, lindsay.hargitai@meduniwien.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	23 January 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 November 2022
Global end of trial reached?	Yes
Global end of trial date	17 November 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To examine the difference in the outcome of GO in patients with moderate-to-severe GO, who receive Tx versus further ATD after suffering their first relapse following the initial decrease in ATD after 6 months. Establish a glucocorticoid scheme before and after Tx in patients with moderate-to-severe EO. The difference will primarily be measured in terms of the Muscle Index score determined through an ultrasound.

Protection of trial subjects:

All patients signed a declaration of consent were safety measures were previously discussed. All patients underwent in long term follow-up with blood analyses.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 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: 14
Worldwide total number of subjects	14
EEA total number of subjects	14

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)	14
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening criteria were required for each patient

Period 1

Period 1 title	Study period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Carer ^[1]

Arms

Are arms mutually exclusive?	Yes
Arm title	Thyroidectomy

Arm description: -

Arm type	Surgery
No investigational medicinal product assigned in this arm	

Arm title	Anti-thyroid drug (ATD)
------------------	-------------------------

Arm description: -

Arm type	Antithyroid drug medicine
Investigational medicinal product name	Anti-thyroid drug (ATD)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral usage, dosage based on hormone levels in the blood

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: Yes

Number of subjects in period 1^[2]	Thyroidectomy	Anti-thyroid drug (ATD)
Started	2	2
Completed	2	2

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Too few patients were enrolled in this study and therefore the study was discontinued.

Baseline characteristics

Reporting groups

Reporting group title	Study period
-----------------------	--------------

Reporting group description: -

Reporting group values	Study period	Total	
Number of subjects	4	4	
Age categorical			
Units: Subjects			
Adults (18-64 years)		4	
Age continuous			
Units: years			
arithmetic mean	46		
full range (min-max)	24 to 56	-	
Gender categorical			
Units: Subjects			
Female	4	4	
Male	0	0	

End points

End points reporting groups

Reporting group title	Thyroidectomy
Reporting group description: -	
Reporting group title	Anti-thyroid drug (ATD)
Reporting group description: -	

Primary: Thyroid antibodies

End point title	Thyroid antibodies ^[1]
End point description:	

End point type	Primary
End point timeframe:	
1 year	

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: Too few patients

End point values	Thyroidectomy	Anti-thyroid drug (ATD)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	2		
Units: IU/L				
number (not applicable)	2.92	26.91		

Statistical analyses

No statistical analyses for this end point

Primary: CAScore

End point title	CAScore ^[2]
End point description:	

End point type	Primary
End point timeframe:	
1 year	

Notes:

[2] - 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: Too few patients

End point values	Thyroidectomy	Anti-thyroid drug (ATD)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	2		
Units: score	3	4		

Statistical analyses

No statistical analyses for this end point

Primary: Quality of Life Score

End point title	Quality of Life Score ^[3]
-----------------	--------------------------------------

End point description:

End point type	Primary
----------------	---------

End point timeframe:

1 year

Notes:

[3] - 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: Too few patients

End point values	Thyroidectomy	Anti-thyroid drug (ATD)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	2		
Units: score	9	11		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Study period

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	25
--------------------	----

Frequency threshold for reporting non-serious adverse events: 0 %

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 adverse events were reported within the whole trial

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 October 2019	Change principal investigators, change last name of study coordinator

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported