



Clinical trial results:

A randomized Phase III study to compare arsenic trioxide (ATO) combined to ATRA and idarubicin versus standard ATRA and anthracycline-based chemotherapy (AIDA regimen) for patient with newly diagnosed, high-risk acute promyelocytic leukemia

Summary

EudraCT number	2015-001151-68
Trial protocol	DE FR NL BE ES IT
Global end of trial date	21 January 2025

Results information

Result version number	v1 (current)
This version publication date	12 June 2026
First version publication date	12 June 2026

Trial information

Trial identification

Sponsor protocol code	TUD-APOLLO-064
-----------------------	----------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02688140
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Technische Universität Dresden
Sponsor organisation address	Helmholtzstraße 10, Dresden, Germany, 01069
Public contact	Coordinating investigator, Technische Universität Dresden, Coordinating investigator, MK1, Bereich Klinische Studien, +49 3514583192, uwe.platzbecker@ukdd.de
Scientific contact	Coordinating investigator, Technische Universität Dresden, Coordinating investigator, MK1, Bereich Klinische Studien, +49 +493514583192, uwe.platzbecker@ukdd.de

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	05 March 2026
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 January 2025
Global end of trial reached?	Yes
Global end of trial date	21 January 2025
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To compare event-free survival (EFS) of the experimental treatment arm including ATO/ATRA and idarubicin with standard treatment based on ATRA plus chemotherapy (AIDA regimen) in newly diagnosed high-risk APL

Protection of trial subjects:

An independent Data safety monitoring board (DSMB) was set in order to oversee the safety of the trial subjects by periodic safety assessments of the trial therapy . The DSMB followed specific guidelines outlined in the DSMB charter.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2015
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	Netherlands: 9
Country: Number of subjects enrolled	Spain: 21
Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	France: 33
Country: Number of subjects enrolled	Germany: 33
Country: Number of subjects enrolled	Italy: 35
Worldwide total number of subjects	133
EEA total number of subjects	133

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)	133
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients with newly diagnosed high-risk acute promyelocytic leukemia (APL/AML M3) at the age of 18 to 65.

Pre-assignment

Screening details:

Assessments from routine diagnostic procedures (before informed consent) could be used for Baseline visit: Assessments (internal or external) of ECG, echocardiography, hepatitis- and HIV serology should not be older than 14 days before randomization. Bone marrow assessments (internal or external) should not be older than 7 days before randomization

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Experimental Arm A (ATRA/ATO)

Arm description:

All-trans retinoic acid and arsenic trioxide (ATRA/ATO) preceded by two doses of idarubicin and followed by four ATRA/ATO consolidation cycles

Arm type	Experimental
Investigational medicinal product name	Trisenox
Investigational medicinal product code	
Other name	arsenic trioxide
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Induction therapy

ATO

Dose: 0.15 mg/kg body weight

Duration: day 5-28 max. up to day 60 after start of IDA

Consolidation cycles I-IV

ATO

Dose: 0.15 mg/kg body weight

Duration: day 1-5 (4wks on/ 4wks off for a total of 4 courses)

Arm title	Control Arm B (AIDA regimen)
------------------	------------------------------

Arm description:

ATRA plus idarubicin induction followed by three chemotherapy consolidation cycles and two years of maintenance

Arm type	standard chemotherapy
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Experimental Arm A (ATRA/ATO)	Control Arm B (AIDA regimen)
Started	68	65
Completed	62	50
Not completed	6	15
Adverse event, serious fatal	5	5
Consent withdrawn by subject	-	1
Adverse event, non-fatal	1	7
Medical decision	-	2

Baseline characteristics

Reporting groups

Reporting group title	Experimental Arm A (ATRA/ATO)
Reporting group description: All-trans retinoic acid and arsenic trioxide (ATRA/ATO) preceded by two doses of idarubicin and followed by four ATRA/ATO consolidation cycles	
Reporting group title	Control Arm B (AIDA regimen)
Reporting group description: ATRA plus idarubicin induction followed by three chemotherapy consolidation cycles and two years of maintenance	

Reporting group values	Experimental Arm A (ATRA/ATO)	Control Arm B (AIDA regimen)	Total
Number of subjects	68	65	133
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)	68	65	133
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	34	30	64
Male	34	35	69

End points

End points reporting groups

Reporting group title	Experimental Arm A (ATRA/ATO)
Reporting group description: All-trans retinoic acid and arsenic trioxide (ATRA/ATO) preceded by two doses of idarubicin and followed by four ATRA/ATO consolidation cycles	
Reporting group title	Control Arm B (AIDA regimen)
Reporting group description: ATRA plus idarubicin induction followed by three chemotherapy consolidation cycles and two years of maintenance	

Primary: Event-free survival (EFS)

End point title	Event-free survival (EFS) ^[1]
End point description: To compare event-free survival (EFS) of the experimental treatment arm including ATO/ATRA and idarubicin with standard treatment based on ATRA plus chemotherapy (AIDA regimen).	
End point type	Primary
End point timeframe: 2-year event-free survival	

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: further information can be found in the publication (see online references)

End point values	Experimental Arm A (ATRA/ATO)	Control Arm B (AIDA regimen)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	68	65		
Units: percent				
number (confidence interval 95%)	88 (81 to 96)	73 (63 to 85)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

During the trial all adverse events CTCAE \geq grade 3 have been documented in the eCRF. AEs needed to be documented from the date of randomisation until 28 days after the date of study termination.

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

Dictionary used

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

Dictionary version	27.1
--------------------	------

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: further information can be found in the publication (see online references)

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 June 2018	France: protocol version 2.2 F, 11.06.2018
26 September 2019	France: Final trial protocol version 2.3 F, 26.09.2019
09 July 2021	Spain: Final trial protocol version 4.0 F, 09.07.2021

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
07 January 2019	Recruitment of new patients was suspended due to supply issues with the investigational medicinal product. Start in the Netherlands: 07.01.2019, Restart: 04.10.2019 Start in Belgium: 07.01.2019, Restart: 18.11.2019 Start in Germany: 05.02.2019, Restart: 08.10.2019 Start in France: 05.02.2019, Restart: 04.10.2019 Start in Italy: 05.02.2019; Restart: 24.02.2020	04 October 2019

Notes:

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/40825164>