



Clinical trial results:

Pilot Study related to the effect of clopidogrel on plasmatic soluble CD40 ligand during systemic lupus erythematosus

Summary

EudraCT number	2014-003733-25
Trial protocol	FR
Global end of trial date	11 September 2017

Results information

Result version number	v1 (current)
This version publication date	18 September 2026
First version publication date	18 September 2026

Trial information

Trial identification

Sponsor protocol code	CHUBX 2013/27
-----------------------	---------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02320357
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CHU de Bordeaux
Sponsor organisation address	12, rue Dubernat, TALENCE, France, 33404 cedex
Public contact	Laetitia LACAZE-BUZY, CHU de BORDEAUX, 33 557821134, laetitia.lacaze-buzy@chu-bordeaux.fr
Scientific contact	Laetitia LACAZE-BUZY, CHU de BORDEAUX, 33 557821134, laetitia.lacaze-buzy@chu-bordeaux.fr

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	15 September 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	11 September 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Clopidogrel is an anti-platelet aggregation agent that exposes the risk of bleeding. Thus, any situation at risk of bleeding at inclusion or during the study will imply a non-inclusion or an adaptation of the protocol.

Protection of trial subjects:

Clopidogrel is an anti-platelet aggregation agent that exposes the risk of bleeding. Thus, any situation at risk of bleeding at inclusion or during the study will imply a non-inclusion or an adaptation of the protocol.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 August 2015
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	France: 18
Worldwide total number of subjects	18
EEA total number of subjects	18

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)	15
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Date of inclusion of first patient: 19-AUG-2015

Date of last visit last patient: 11-SEP-2017

3 centers in France participated in the study

Pre-assignment

Screening details:

-Patients 18 years of age and older

-Diagnosis of SLE according to revised criteria of American College of Rheumatology

-Being affiliated to health insurance

-Having signed an informed consent

Period 1

Period 1 title	Period 1
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Clopidogrel
Arm description: -	
Arm type	Single arm study
Investigational medicinal product name	Clopidogrel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally at the dosage of one 75 mg tablet per day.

Number of subjects in period 1	Clopidogrel
Started	18
Completed	18

Period 2

Period 2 title	Period 2
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Clopidogrel
------------------	-------------

Arm description:

Patients receiving clopidogrel over a 12 week period

Arm type	Single arm study
----------	------------------

Investigational medicinal product name	Clopidogrel
--	-------------

Investigational medicinal product code	
--	--

Other name	
------------	--

Pharmaceutical forms	Tablet
----------------------	--------

Routes of administration	Oral use
--------------------------	----------

Dosage and administration details:

Administered orally at the dosage of one 75 mg tablet per day.

Number of subjects in period 2	Clopidogrel
Started	18
Completed	18

Baseline characteristics

Reporting groups

Reporting group title

Period 1

Reporting group description: -

Reporting group values	Period 1	Total	
Number of subjects	18	18	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
arithmetic mean	48.8		
standard deviation	± 16.4	-	
Gender categorical			
Units: Subjects			
Female	15	15	
Male	3	3	

End points

End points reporting groups

Reporting group title	Clopidogrel
Reporting group description: -	
Reporting group title	Clopidogrel
Reporting group description: Patients receiving clopidogrel over a 12 week period	

Primary: Decrease of plasmatic sCD40L levels

End point title	Decrease of plasmatic sCD40L levels
End point description:	
End point type	Primary
End point timeframe: At 12 weeks	

End point values	Clopidogrel	Clopidogrel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	15		
Units: percent				
arithmetic mean (standard deviation)	80.8 ($\pm$ 70.7)	65.1 ($\pm$ 39.4)		

Statistical analyses

Statistical analysis title	Soluble CD40L: mixed model analysis
Statistical analysis description: Slope change model at D7 and S12 with random intercept	
Comparison groups	Clopidogrel v Clopidogrel
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3492
Method	Mixed models analysis

Secondary: Measurements of inflammation markers (CRP)

End point title	Measurements of inflammation markers (CRP)
End point description:	
End point type	Secondary

End point timeframe:

At 12 weeks

End point values	Clopidogrel			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: milligram(s)/litre				
arithmetic mean (standard deviation)	3.3 ($\pm$ 3.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Platelet activation markers - Platelet volume

End point title	Platelet activation markers - Platelet volume
End point description:	
End point type	Secondary
End point timeframe:	
At 12 weeks	

End point values	Clopidogrel			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: fluid ounce				
arithmetic mean (standard deviation)	8.3 ($\pm$ 0.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Platelet/circulating mononuclear cells aggregates - Aggregates CD3+ platelets

End point title	Platelet/circulating mononuclear cells aggregates - Aggregates CD3+ platelets
End point description:	
End point type	Secondary
End point timeframe:	
At 12 weeks	

End point values	Clopidogrel	Clopidogrel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	15		
Units: percent				
arithmetic mean (standard deviation)	28.2 (± 8.4)	27.2 (± 9.4)		

Statistical analyses

Statistical analysis title	Agreg evolution CD3+ platelets
Statistical analysis description:	
Slope change model at D0 and S12 with random intercept	
Comparison groups	Clopidogrel v Clopidogrel
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9362
Method	Mixed models analysis

Secondary: T lymphocytes activation

End point title	T lymphocytes activation
End point description:	
End point type	Secondary
End point timeframe:	
At 12 weeks	

End point values	Clopidogrel			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: percent				
arithmetic mean (standard deviation)	23.3 (± 10.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Measurements of complement protein - C3 weight assay

End point title	Measurements of complement protein - C3 weight assay
End point description:	
End point type	Secondary
End point timeframe:	
At 12 weeks	

End point values	Clopidogrel			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: gram(s)/litre				
arithmetic mean (standard deviation)	1.0 ($\pm$ 0.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Measurements of complement protein - C4 weight assay

End point title	Measurements of complement protein - C4 weight assay
End point description:	
End point type	Secondary
End point timeframe:	
At 12 weeks	

End point values	Clopidogrel			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: gram(s)/litre				
arithmetic mean (standard deviation)	0.2 ($\pm$ 0.1)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Overall study

Adverse event reporting additional description:

These adverse events are described by Preferred Terms (PT).

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

Dictionary used

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

Dictionary version	21.1
--------------------	------

Reporting groups

Reporting group title	Clopidogrel
-----------------------	-------------

Reporting group description: -

Serious adverse events	Clopidogrel		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 18 (11.11%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Reproductive system and breast disorders			
Menorrhagia (10027313)	Additional description: Menorrhagia (10027313)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Respiratory tract infection viral (10062106)	Additional description: Respiratory tract infection viral (10062106)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Clopidogrel		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 18 (94.44%)		
Vascular disorders			
Haematoma (10018852)	Additional description: Haematoma (10018852)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 18 (16.67%)		
occurrences (all)	3		
Varicose vein (10046996)	Additional description: Varicose vein (10046996)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 18 (11.11%)		
occurrences (all)	2		
Reproductive system and breast disorders			
Cervical dysplasia (10008263)	Additional description: Cervical dysplasia (10008263)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Menstrual disorder (10027327)	Additional description: Menstrual disorder (10027327)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea (10013968)	Additional description: Dyspnoea (10013968)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Epistaxis (10015090)	Additional description: Epistaxis (10015090)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Subcutaneous haematoma (10042345)	Additional description: Subcutaneous haematoma (10042345)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Nervous system disorders			
Headache (10019211)	Additional description: Headache (10019211)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Epilepsy (10015037)	Additional description: Epilepsy (10015037)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Sciatica (10039674)	Additional description: Sciatica (10039674)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Aplasia pure red cell (10002965)	Additional description: Aplasia pure red cell (10002965)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Eye disorders			
Conjunctivitis allergic (10010744)	Additional description: Conjunctivitis allergic (10010744)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Abnormal sensation in eye (10000173)	Additional description: Abnormal sensation in eye (10000173)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Gastrointestinal disorders			
Dyspepsia (10013946)	Additional description: Dyspepsia (10013946)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Functional gastrointestinal disorder (10071275)	Additional description: Functional gastrointestinal disorder (10071275)		

alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Toothache (10044055)	Additional description: Toothache (10044055)		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Skin and subcutaneous tissue disorders			
Eczema (10014184)	Additional description: Eczema (10014184)		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 18 (11.11%) 2		
Ecchymosis (10014080)	Additional description: Ecchymosis (10014080)		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 18 (11.11%) 2		
Erythema (10015150)	Additional description: Erythema (10015150)		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Skin haemorrhage (10064265)	Additional description: Skin haemorrhage (10064265)		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Rash (10037844)	Additional description: Rash (10037844)		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Photosensitivity reaction (10034972)	Additional description: Photosensitivity reaction (10034972)		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Renal and urinary disorders			

Pollakiuria (10036018) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Pollakiuria (10036018)		
	1 / 18 (5.56%) 1		
Urine odour abnormal (10057135) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Urine odour abnormal (10057135)		
	1 / 18 (5.56%) 1		
Endocrine disorders Thyroid mass (10058900) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Thyroid mass (10058900)		
	1 / 18 (5.56%) 1		
Musculoskeletal and connective tissue disorders Arthralgia (10003239) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Sjogren's syndrome (10040767) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Pain in extremity (10033425) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Tenosynovitis (10043261) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Tendonitis (10043255) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Arthralgia (10003239)		
	7 / 18 (38.89%) 7		
	Additional description: Sjogren's syndrome (10040767)		
	1 / 18 (5.56%) 1		
	Additional description: Pain in extremity (10033425)		
	1 / 18 (5.56%) 1		
	Additional description: Tenosynovitis (10043261)		
	3 / 18 (16.67%) 3		
	Additional description: Tendonitis (10043255)		
	2 / 18 (11.11%) 2		
Infections and infestations			

Bronchitis (10006451) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Bronchitis (10006451)		
	3 / 18 (16.67%) 3		
Gastroenteritis (10017888) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Gastroenteritis (10017888)		
	2 / 18 (11.11%) 2		
Gingivitis (10018292) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Gingivitis (10018292)		
	1 / 18 (5.56%) 1		
Sinusitis (10040753) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Sinusitis (10040753)		
	2 / 18 (11.11%) 2		
Pharyngitis (10034835) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Pharyngitis (10034835)		
	1 / 18 (5.56%) 1		
Nasopharyngitis (10028810) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Nasopharyngitis (10028810)		
	3 / 18 (16.67%) 3		
Tinea versicolour (10056131) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Tinea versicolour (10056131)		
	1 / 18 (5.56%) 1		
Vulvovaginal mycotic infection (10064899) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Vulvovaginal mycotic infection (10064899)		
	1 / 18 (5.56%) 1		

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

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/33152483>

<http://www.ncbi.nlm.nih.gov/pubmed/29635077>