



Clinical trial results:

Efficacy and tolerance of the association of Baricitinib (4mg) and phototherapy versus phototherapy in adults with progressive vitiligo: a randomized double blind prospective study

Summary

EudraCT number	2020-005079-12
Trial protocol	FR
Global end of trial date	24 April 2023

Results information

Result version number	v1 (current)
This version publication date	26 June 2026
First version publication date	26 June 2026

Trial information

Trial identification

Sponsor protocol code	CHUBX2019/21
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04822584
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CHU de Bordeaux
Sponsor organisation address	12 rue Dubernat, Talence, France, 33400
Public contact	Julien SENESCHAL, Centre Hospitalier Universitaire de Bordeaux, +33 05 56 79 49 63, julien.seneschal@chu-bordeaux.fr
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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	27 July 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 April 2023
Global end of trial reached?	Yes
Global end of trial date	24 April 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of the combination of baricitinib (orally) 4 mg/d + UVB TL01 (twice a week) by evaluating the percentage of skin repigmentation after 36 weeks of treatment using the VASI score in patients with vitiligo.

Protection of trial subjects:

The important identified and important potential risks are recognized for baricitinib and will be followed carefully in this study. Immediate risks associated with phototherapy are the occurrence of erythema that will be evaluated at each phototherapy visit. Long-term risks are cataract risk that will be prevented by wearing safety glasses. The risk of genital skin carcinoma will be prevented by wearing underclothes. The coordinating investigator will constantly monitor, assess and document risks and ensure that they can be managed satisfactorily.

The investigator is responsible for the reporting of adverse events which occur from the date of signature of the consent until the end of participation of the patient. In this study, all the adverse events must be reported.

In some circumstances, it may be necessary to temporarily interrupt treatment as a result of AEs or abnormal laboratory values that may have an unclear relationship to investigational product. In those cases investigational product may be restarted at the discretion of the investigator.

In order to ensure the safety of the participants, the following therapies will not be permitted during the course of the study : therapies that could induce photosensitivity, high exposition to natural sun.

An dermatological exam (to verify the absence of other skin disorders associated with vitiligo and the absence of skin carcinoma/melanoma) will be performed at each visits : randomisation visit, follow-up visit at week 12, follow-up visit at week 24, end of treatment visit (week 36), end of study visit (week 48)

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 April 2021
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	France: 49
Worldwide total number of subjects	49
EEA total number of subjects	49

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)	47
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment will be carried out within the out-patient setting in the different Departments of Dermatology participating in the study.

Pre-assignment

Screening details:

In total, 61 patients were selected, of which 49 were randomized

Period 1

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

Blinding implementation details:

Recruitment will be carried out within the out-patient setting in the different Departments of Dermatology participating in the study.

A feasibility study regarding inclusion and non inclusion criteria has been conducted in these four departments, with a great expertise in the management of vitiligo, to ensure that a sufficient number of patients could be included in this research protocol. The four departments have access to blood and skin samples from vitiligo patients. It is important to me

Arms

Are arms mutually exclusive?	Yes
Arm title	Baricitinib

Arm description:

The treatment evaluated is baricitinib at a dosage of 4 mg/day for 36 weeks, combined with phototherapy twice a week started 12 weeks after the start of baricitinib and continued for 24 weeks. We have decided to test the higher dose currently tested in another chronic inflammatory skin disorders called atopic dermatitis that showed in phase II and phase III significant efficacy with a good safety profile.

Dosage schedule: 4 mg/day.

Arm type	Experimental
Investigational medicinal product name	BARICITINIB
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Once daily dosing for 36 weeks

Arm title	Placebo
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Arm description:

Placebo of baricitinib associated with UVB TL01 phototherapy will be used. Placebo of baricitinib will be started 12 weeks before the start of phototherapy and will be continued for 36 weeks.

Arm type	Placebo
Investigational medicinal product name	PLACEBO
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet per day until 36 weeks

Number of subjects in period 1	Baricitinib	Placebo
Started	37	12
Completed	33	9
Not completed	4	3
Consent withdrawn by subject	3	1
Physician decision	1	-
Lost to follow-up	-	2

Baseline characteristics

Reporting groups

Reporting group title	Baricitinib
Reporting group description: The treatment evaluated is baricitinib at a dosage of 4 mg/day for 36 weeks, combined with phototherapy twice a week started 12 weeks after the start of baricitinib and continued for 24 weeks. We have decided to test the higher dose currently tested in another chronic inflammatory skin disorders called atopic dermatitis that showed in phase II and phase III significant efficacy with a good safety profile. Dosage schedule: 4 mg/day.	
Reporting group title	Placebo
Reporting group description: Placebo of baricitinib associated with UVB TL01 phototherapy will be used. Placebo of baricitinib will be started 12 weeks before the start of phototherapy and will be continued for 36 weeks.	

Reporting group values	Baricitinib	Placebo	Total
Number of subjects	37	12	49
Age categorical Units: Subjects			
Adults (18-64 years)	32	11	43
From 65-84 years	5	1	6
Age continuous Units: years			
arithmetic mean	47.1	52.3	
full range (min-max)	36.9 to 52.6	42 to 60.8	-
Gender categorical Units: Subjects			
Female	28	7	35
Male	9	5	14
Fitzpatrick skin			
The Fitzpatrick skin type (or phototype) is a classification system that categorizes human skin based on its response to ultraviolet (UV) radiation, particularly in terms of tanning and burning. Type I: Very fair skin, often with red or blond hair and blue or green eyes. Always burns, never tans. Type II: Fair skin, usually with blue or green eyes. Burns easily, tans minimally. Type III: Medium skin tone. Sometimes burns, tans uniformly. Type IV: Olive or light brown skin. Burns minimally, tans easily. Type V: Brown skin. Rarely burns, tans darkly. Type VI: Dark brown or black skin. Nev			
Units: Subjects			
Type I	0	0	0
Type II	6	3	9
Type III	22	7	29
Type IV:	2	0	2
Type V:	1	0	1
Not recorded	6	2	8

Subject analysis sets

Subject analysis set title	Per protocol
Subject analysis set type	Per protocol

Reporting group values	Per protocol		
Number of subjects	41		
Age categorical			
Units: Subjects			
Adults (18-64 years)	35		
From 65-84 years	6		
Age continuous			
Units: years			
arithmetic mean	21.4		
full range (min-max)			
Gender categorical			
Units: Subjects			
Female	31		
Male	10		
Fitzpatrick skin			
The Fitzpatrick skin type (or phototype) is a classification system that categorizes human skin based on its response to ultraviolet (UV) radiation, particularly in terms of tanning and burning. Type I: Very fair skin, often with red or blond hair and blue or green eyes. Always burns, never tans. Type II: Fair skin, usually with blue or green eyes. Burns easily, tans minimally. Type III: Medium skin tone. Sometimes burns, tans uniformly. Type IV: Olive or light brown skin. Burns minimally, tans easily. Type V: Brown skin. Rarely burns, tans darkly. Type VI: Dark brown or black skin. Never burns, tans very darkly.			
Units: Subjects			
Type I	0		
Type II	6		
Type III	22		
Type IV:	2		
Type V:	1		
Not recorded	0		

End points

End points reporting groups

Reporting group title	Baricitinib
Reporting group description: The treatment evaluated is baricitinib at a dosage of 4 mg/day for 36 weeks, combined with phototherapy twice a week started 12 weeks after the start of baricitinib and continued for 24 weeks. We have decided to test the higher dose currently tested in another chronic inflammatory skin disorders called atopic dermatitis that showed in phase II and phase III significant efficacy with a good safety profile. Dosage schedule: 4 mg/day.	
Reporting group title	Placebo
Reporting group description: Placebo of baricitinib associated with UVB TL01 phototherapy will be used. Placebo of baricitinib will be started 12 weeks before the start of phototherapy and will be continued for 36 weeks.	
Subject analysis set title	Per protocol
Subject analysis set type	Per protocol
Subject analysis set description: All subjects receiving the product and without any major protocol deviations (Per protocol)	

Primary: Mean percentage change in total Vitiligo Area Scoring Index (VASI) score from baseline to week 36

End point title	Mean percentage change in total Vitiligo Area Scoring Index (VASI) score from baseline to week 36
End point description: The mean variation in percentage from baseline in VASI score after 36 weeks as well as its 95% unilateral confidence interval will be calculated in the patients of the experimental group (baricitinib + UVB TL01). This analysis will be performed per protocol, that is, only in patients who have correctly followed the study protocol, and on available data. No statistical comparison tests will be performed between the experimental group and the control group in this proof-of-concept phase 2 study.	
End point type	Primary
End point timeframe: Baseline to week 36	

End point values	Baricitinib	Placebo	Per protocol	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	31	10	31	
Units: %				
arithmetic mean (confidence interval 95%)	49.1 (-47.7 to 91.1)	10.1 (-115.9 to 68.1)	49.1 (36.5 to 61.6)	

Statistical analyses

Statistical analysis title	Mean decrease and IC of the mean decrease of T-VAS
Statistical analysis description: The hypothesis that this percentage is higher than 42.9% (repigmented surface threshold (as shown in Hamzavi I et al(11)) below which the treatment would be	

considered not efficacious enough will be tested by a one-sample Student's t test of an observed vs. a theoretical mean, at the 5% unilateral type I error.

Comparison groups	Baricitinib v Placebo
Number of subjects included in analysis	41
Analysis specification	Post-hoc
Analysis type	superiority ^[1]
P-value	< 0.1619
Method	Student paired Test
Parameter estimate	Mean difference (net)
Point estimate	49.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	36.5
upper limit	61.6
Variability estimate	Standard deviation
Dispersion value	34.2

Notes:

[1] - Omnibus analysis: All reporting groups, Selection of Reporting groups: BARICITINIB

Adverse events

Adverse events information

Timeframe for reporting adverse events:

site personnel recorded any change in the condition(s) and any new conditions as AEs. Investigators should record their assessment of the potential relatedness of each AE to investigational product, via eCRF.

Adverse event reporting additional description:

The investigator interpreted and documented whether or not an AE had a reasonable possibility of being related to study treatment, study device, or a study procedure, taking into account the disease, concomitant treatment, or pathologies.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.0
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Reporting groups

Reporting group title	Barcitinib
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Reporting group description: -

Reporting group title	placebo
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Reporting group description: -

Serious adverse events	Barcitinib	placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 37 (5.41%)	1 / 12 (8.33%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
back pain			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Viral infection			

subjects affected / exposed	0 / 37 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Baricitinib	placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 37 (64.86%)	7 / 12 (58.33%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 37 (5.41%)	0 / 12 (0.00%)	
occurrences (all)	2	0	
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	2 / 37 (5.41%)	1 / 12 (8.33%)	
occurrences (all)	2	1	
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
MALAISE			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
PYREXIA			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	2 / 37 (5.41%)	0 / 12 (0.00%)	
occurrences (all)	2	0	
Cough			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Dyspnoea			

subjects affected / exposed	0 / 37 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Dyspnoea exertional			
subjects affected / exposed	0 / 37 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Investigations			
Weight increased			
subjects affected / exposed	2 / 37 (5.41%)	0 / 12 (0.00%)	
occurrences (all)	2	0	
Blood bilirubin increased			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Transaminases increased			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
blood creatine phosphokinase increased	Additional description: CPK Increase		
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Fibula fracture			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Ligament sprain	Additional description: Ankle sprain And Sprained ankle		
subjects affected / exposed	0 / 37 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	2	
Road traffic accident	Additional description: Motor cycling accident		
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Limb injury	Additional description: open wound of finger(s)		
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			

Headache subjects affected / exposed occurrences (all)	3 / 37 (8.11%) 4	1 / 12 (8.33%) 1	
Migraine subjects affected / exposed occurrences (all)	2 / 37 (5.41%) 2	0 / 12 (0.00%) 0	
Neuralgia subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	1 / 12 (8.33%) 1	
Presyncope subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1	0 / 12 (0.00%) 0	
Blood and lymphatic system disorders NEUTROPENIA subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1	0 / 12 (0.00%) 0	
Eye disorders dry eye subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1	0 / 12 (0.00%) 0	
VISUAL ACUITY REDUCED subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1	0 / 12 (0.00%) 0	
Gastrointestinal disorders ABDOMINAL PAIN subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1	0 / 12 (0.00%) 0	
APHTHOUS ULCER subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1	0 / 12 (0.00%) 0	
CONSTIPATION subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1	0 / 12 (0.00%) 0	
DIARRHOEA subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1	0 / 12 (0.00%) 0	
DYSPEPSIA			

subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
HAEMORRHOIDS			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
SALIVARY GLAND CALCULUS			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Dermatitis acneiform	Additional description: Acneiform eruption		
subjects affected / exposed	2 / 37 (5.41%)	0 / 12 (0.00%)	
occurrences (all)	2	0	
Pruritus	Additional description: Itching and itchy scalp		
subjects affected / exposed	2 / 37 (5.41%)	0 / 12 (0.00%)	
occurrences (all)	2	0	
Erythema	Additional description: Erythema facial		
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
ACARODERMATITIS			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
BRONCHITIS			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
COVID-19			
subjects affected / exposed	5 / 37 (13.51%)	3 / 12 (25.00%)	
occurrences (all)	7	3	
HERPES SIMPLEX			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
HERPES VIRUS INFECTION			

subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
NASOPHARYNGITIS			
subjects affected / exposed	0 / 37 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
PAPILLOMA VIRAL INFECTION			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
RHINITIS			
subjects affected / exposed	0 / 37 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
TONSILLITIS			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
URINARY TRACT INFECTION			
subjects affected / exposed	3 / 37 (8.11%)	0 / 12 (0.00%)	
occurrences (all)	4	0	
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	2 / 37 (5.41%)	0 / 12 (0.00%)	
occurrences (all)	2	0	
Hypertriglyceridaemia			
subjects affected / exposed	1 / 37 (2.70%)	0 / 12 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 September 2021	1. Addition of a label indicating the box number to which the baricitinib 4mg/placebo vial is associated (additional label on the primary packaging) by the coordinating pharmacy of Bordeaux University Hospital. 2. Addition of a label on the box (additional label on the secondary packaging) giving the box number, by the coordinating pharmacy at Bordeaux University Hospital. 3. Update of the paragraph on product dispatch and management (chapter 8.2.5) concerning the number of treatments sent to the centers.

Notes:

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/39841460>