Clinical trial results:
A double-blind, randomized, multicenter study evaluating 200 mg versus 600 mg of Mifepristone on pain in voluntary abortion by drug prior to 7 SA.

Summary

EudraCT number	2017-004083-35
Trial protocol	FR
Global end of trial date	04 April 2023

Results information

Result version number	v1 (current)
This version publication date	11 June 2026
First version publication date	11 June 2026

Trial information

Trial identification

Sponsor protocol code	2017-53

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03659045
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Assistance - Publique Hôpitaux de Marseille
Sponsor organisation address	80 rue Brochier, Marseille, France, 13354
Public contact	Marjorie Saccone, Assistance - Publique Hôpitaux de Marseille, +33 0491381966, marjorie.saccone@ap-hm.fr
Scientific contact	Marjorie Saccone, Assistance - Publique Hôpitaux de Marseille, +33 0491381966, marjorie.saccone@ap-hm.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	04 April 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 April 2023
Global end of trial reached?	Yes
Global end of trial date	04 April 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this research is to compare the efficacy in reducing the pain of two doses of Mifegyne during medicinal abortion before 7 Weeks of amenorrhea (600 versus 200 mg).

Protection of trial subjects:

Analgesics

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 January 2019
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: 320
Worldwide total number of subjects	320
EEA total number of subjects	320

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)	320
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Critères d'inclusion : Femme âgée de 18 ans ou plus; Présentant une grossesse intra-utérine unique, dont le terme est inférieur à 7 SA le jour de la prise de Mifépristone, estimé par échographie avec une mesure de la longueur crânio-caudale inférieure ou égale à 10 millimètres ; Désirant une IVG médicamenteuse en milieu hospitalier ; Ayant signé CE

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, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	Groupe 600 mg

Arm description: -

Arm type	Experimental
Investigational medicinal product name	MIFEPRISTONE
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Buccal tablet
Routes of administration	Buccal use

Dosage and administration details:

3 comprimés de 200 mg par voie orale

Arm title	Goupe 200 mg

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Groupe 600 mg	Goupe 200 mg
Started	160	160
Completed	160	160

Baseline characteristics

Reporting groups	
Reporting group title	Groupe 600 mg
Reporting group description: -	
Reporting group title	Goupe 200 mg
Reporting group description: -	

Reporting group values	Groupe 600 mg	Goupe 200 mg	Total
Number of subjects	160	160	320
Age categorical Units: Subjects			
Femme majeur	160	160	320
Gender categorical Units: Subjects			
FEMALE	160	160	320

End points

End points reporting groups	
Reporting group title	Groupe 600 mg
Reporting group description: -	
Reporting group title	Goupe 200 mg
Reporting group description: -	

Primary: Evaluation de la douleur	
End point title	Evaluation de la douleur
End point description:	
End point type	Primary
End point timeframe:	
5h suivant la prise de misoprostol	

End point values	Groupe 600 mg	Goupe 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	160	160		
Units: NA	160	160		

Statistical analyses

Statistical analysis title	Critère principal
Statistical analysis description:	
La moyenne du niveau de douleur sur les 5 temps horaires initiaux : La moyenne est calculée sur les 5 EN de la base de données. doul_mean = Mean (douleur_1h, douleur_2h, douleur_3h, douleur_4h, douleur_5h) Pour rappel, la moyenne est calculée sur les données renseignées : - si aucune donnée sur les 5 EN : pas de calcul, donnée manquante. - si 0 ou 4 données manquantes, la moyenne est calculée sur les données renseignées.	
Comparison groups	Groupe 600 mg v Goupe 200 mg
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	≤ 0 [2]
Method	Mann-Whitney

Notes:

[1] - L’analyse est réalisée en intention de traiter sur un set ‘modified intent-to-treat’

[2] - Les P-valeurs sont produites à titre indicatif seulement.

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

No timeframe for adverse event reporting by the investigator to the promotor
Timeframe for serious adverse event reporting by the investigator to the promotor : within 24 hours

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

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: Les évènements indésirables non graves ont été recueillis pour cette étude et correspondent aux critères de jugements.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 October 2018	La modification porte sur le conditionnement et l'étiquetage des unités thérapeutiques afin de respecter la mise en aveugle.
09 July 2019	La modification porte sur un critère de non inclusion
07 January 2020	Changement d'investigateur Principal dans un centre associé
21 October 2020	Mise à jour du protocole, du document d'information et du formulaire de consentement conformément au RGPD.
03 February 2021	Prolongation de la durée d'étude
07 July 2021	Suspension temporaire des inclusions à partir du 06/07/2021.
09 August 2022	Reprise des inclusions Modification de critères de non inclusion Correction d'une erreur dans le critère de jugement principal Prolongation de la durée d'étude Mise à jour du protocole et de la note d'information patiente
08 February 2023	mise à jour de la version du RCP de la MYFEGYNE 200mg + Ajout d'un critère de non inclusion + Ajout d'un critère d'exclusion

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
06 July 2021	Suspension temporaire des inclusions à partir du 06/07/2021. Motif de l'arrêt : conformément aux engagements pris par l'APHM suite à une inspection dans l'attente d'une mise en conformité de la cellule vigilance.	09 August 2022

Notes:

Limitations and caveats

None reported