ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: May 24, 2021

ClinicalTrials.gov ID: [Not yet assigned]

Study Identification

Unique Protocol ID:	LPI011
Brief Title:	Effectiveness and Safety of Combination Mifepristone/Misoprostol for Medical Abortion (MiMAC)
Official Title:	Prospective Non Interventional Phase IV Multi-centre Canadian Study on the Effectiveness and Safety of Combination Mifepristone/Misoprostol for Medical Abortion Under 63 Days Gestation
Secondary IDs:	

Study Status

Record Verification:	May 2021
Overall Status:	Not yet recruiting
Study Start:	July 15, 2021 [Anticipated]
Primary Completion:	June 30, 2023 [Anticipated]
Study Completion:	December 30, 2023 [Anticipated]

Sponsor/Collaborators

Sponsor:	Linepharma International LTD
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
U.S. FDA IND/IDE:	
Human Subjects Review:	Board Status: Pending
Data Monitoring:	Yes
FDA Regulated Intervention:	No

Study Description

Brief Summary:	National multi centre non interventional study aiming at investigating the effectiveness and safety of the combination mifepristone-misoprostol prescribed

	in Canada to women for medical termination of pregnancy at or before 63 days gestational age through a multi-center prospective non interventional study design.
Detailed Description:	Primary Objectives Effectiveness of mifepristone-misoprostol for medical abortion at or prior to 63 days gestational age, defined as complete abortion without further intervention within 14 days of mifepristone administration Safety of mifepristone-misoprostol safety for medical abortion at or prior to 63 days gestational age, defined as the rate of significant Treatment Emergent Adverse Event, a composite outcome of the following events: 1. Hospital Admission; 2. Treatment in Emergency Room; 3. Blood Transfusion; 4. Infection requiring IV Antibiotics, Admission, or Surgical debridement; 5. Death; 6. Ongoing intrauterine pregnancy; 7. Ectopic pregnancy. Secondary objectives To determine the rate of ongoing pregnancy within 14 days after the administration of mifepristone To determine the rate of surgical aspiration performed at the follow-up and time since mifepristone administration To determine the reasons for surgical aspiration To evaluate the follow-up rate To evaluate the delay between the scheduled and actual treatment administration To determine the overall safety profile of mifepristone-misoprostol combination To evaluate the impact of the demographic characteristics (prescription site, region, gestational age) on effectiveness and safety To evaluate the impact of gestational age on effectiveness and safety To evaluate the impact of treatment self-administration on effectiveness and safety To evaluate the impact of the method and timing of determining gestational age on effectiveness and safety Study population Study perormed on a stratified sample of sequential participants (n=3,000) who fulfill trial selection criteria and provide informed consent across a range of clinical practices in Canada (n=30)

Conditions

Conditions:	Medical Abortion
Keywords:	

Study Design

Study Type:	Observational
Observational Study Model:	Cohort
Time Perspective:	Prospective
Biospecimen Retention:	None Retained
Biospecimen Description:	
Enrollment:	3000 [Anticipated]
Number of Groups/Cohorts:	1

Groups and Interventions

Intervention Details:
Drug: Mifepristone-Misoprostol
Non interventional design.

Outcome Measures

Primary Outcome Measure:

1. Effectivenessof mifepristone-misoprostol for medical abortion at or prior to 63 days of gestational age
   defined as complete abortion without further intervention within 14 days of mifepristone administration.

   [Time Frame: 14 to 28 days]

2. Safety of mifepristone-misoprostol for medical abortion at or prior to 63 days gestational age
   defined as the rate of significant Treatment Emergent Adverse Event, a composite outcome of the following events: 1. Hospital Admission; 2. Treatment in Emergency Room; 3. Blood Transfusion; 4. Infection requiring IV Antibiotics, Admission, or Surgical debridement; 5. Death; 6. Ongoing intrauterine pregnancy; 7. Ectopic pregnancy.

   [Time Frame: 14 to 28 days]

Secondary Outcome Measure:

3. Rate of ongoing pregnancy
   the frequency of ongoing pregnancy documented at the first follow-up visit within 14 days after mifepristone administration. The method used to document the completion of abortion and the intervention proposed in case of ongoing pregnancy will also be recorded.

   [Time Frame: 14 to 28 days]

4. Rate of surgical aspiration
   Descirption of the frequency (n and percentage of surgical abortion)

   [Time Frame: 14-28 days]

5. Reasons for surgical aspiration
   frequency of the following indications : Ongoing pregnancy, Persistent gestational sac, Retained products of conception, Severe bleeding , Pelvic pain, Suspicion of ectopic pregnancy, others

   [Time Frame: 14-28 days]

6. Delay between the scheduled and actual treatment administration
   Measure of the time (in days) between the date scheduled at the initial visit and the actual date of administration of mifepristone. Administration performed within 24 hours of the treatment scheduled time is considered as on time (0 days).

   Measure of the time (in hour) between the actual administration of misoprostol and the actual administration of mifepristone.

   Description of the rate of mifepristone administration after 63 weeks of gestational age

   [Time Frame: 14 days]

7. Overall safety profile of mifepristone-misoprostol combination
   frequency of the following:TEAEs /STEAEs included in the composite criteria, Hysterectomy, Asthma resistant to common drugs, Cardiovascular event, Skin rash, angioeodema, anaphylaxis,, Seizure, Suicide, Potential consequences of ongoing pregnancy exposed to mifepristone +/- misoprostol, All other SAEs described by System, Organ, Class (SOC) and Preferred Term (PT) , All other TEAE described by SOC and PT

   [Time Frame: 14-28 days]

8. Impact of the demographic characteristics (prescription site, region, gestational age) on effectiveness and safety
   comparison of the rates of the primary effectiveness and safety endpoints according to the following stratified parameters: Health Care Professional's site: 1) Abortion Clinic 2) Hospital 3) Private practice 4) Other Type of Health Care Professional: 1) Specialist, 2) General Practitioner, 3) Nurse, 4) Other Participant location : rural vs. urban Geographic area of the prescribing site according to Canadian province

   [Time Frame: 14-28 days]

9. Impact of gestational age on effectiveness and safety
   comparison of the rates of the primary effectiveness and safety endpoints according to gestational age at the time of actual mifepristone administration according to the following stratification:

≤ 35 days 36-49 days 50-63 days > 63 days

[Time Frame: 14-28 days]

10. Impact of treatment self-administration on effectiveness and safety
comparison of the rates of the primary effectiveness and safety endpoints according to the location at which mifepristone is taken: At the study site At home

[Time Frame: 14-28 days]

11. Impact of the method and timing of determining gestational age on effectiveness and safety
comparison of the rates of the primary effectiveness and safety endpoints according to the fact that ultra-sonography was performed (or not) to confirm gestational age and rule out ectopic pregnancy.

Description of the mean timing of gestational age determination by ultra-sonography (in weeks of amenorrhea) according to the primary endpoints (existence of complete abortion (yes/no) and of significant treatment emergent adverse event (yes/no)).

[Time Frame: 14-28 days]

12. Follow-up rate
The follow-up rate will be assessed up to 28 days after mifepristone administration by describing the rate of:

Attendance at the in-person follow-up visit between 7 and 14 days after mifepristone administration Attendance at a remote follow-up visit (phone call) up to 28 days after mifepristone administration Loss to follow-up (inability to contact participant up to 28 days following mifepristone administration)

[Time Frame: 28 days]

Eligibility

Study Population:	stratified sample of sequential pregnant women requesting medical abortion under 63 days of gestation, who fulfill trial selection criteria and provide informed consent across a range of clinical practices in Canada.
Sampling Method:	Non-Probability Sample
Minimum Age:	16 Years
Maximum Age:	55 Years
Sex:	Female
Gender Based:	Yes pregnant women
Accepts Healthy Volunteers:	No
Criteria:	Inclusion criteria Women who: request elective pregnancy termination in one of the sites participating into the study are prescribed mifepristone-misoprostol for this purpose provide informed consent to participate in the study. Exclusion Criteria: Participant who is unable to understand or comply with Health Care Professional instructions or medical abortion regimen Participant who is unable or unwilling to provide written informed consent.

Contacts/Locations

Central Contact Person:	Delphine JAQUET, MD PhD Telephone: +33786299178

Email: d.jaquet@linepharma-lab.com

Central Contact Backup: Marion ULMANN, PhD
Telephone: +14379981980
Email: m.ulmann@linepharma-lab.com

Study Officials: Dustin COSTESCU, MDMS FRCSC
Study Principal Investigator
McMaster University Medical Centre - Hamilton ON Canada

Locations:

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information: