A randomized, placebo-controlled, double-blind, parallel-group, multi-center, exploratory dose-response study to assess the efficacy and safety of different oral doses of BAY1128688 in women with symptomatic endometriosis over a 12-week treatment period

Published: 12-09-2017
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Purpose of the study is to test whether study drug BAY1128688 brings relief for pain to women with endometriosis and if so to get a first impression which dose(s) work best.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive tract disorders NEC
Study type	Interventional

Summary

ID

NL-OMON46660

Source
ToetsingOnline

Brief title
AKRENDO1

Condition

- Reproductive tract disorders NEC

Synonym
pain during intercourse ('dyspareunia') and non-cyclic pelvic pain., Well-accepted lay language synomyms for endometriosis are not known to us. Endometriosis describes the

presence of endometrium elsewhere than in the lining of the uterus. It is associated with pelvic pain during menstruation called 'dysmenorrhea'

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer AG

Intervention

Keyword: Pain relief, Symptomatic endometriosis

Outcome measures

Primary outcome

Primary objective: Explore the dose response relationship of different doses of

BAY 1128688 compared to placebo in the treatment of endometriosis-related

symptoms over a 12-week treatment period

Secondary outcome

Secondary objective: Assessment of safety and tolerability of BAY 1128688 over

a 12-week treatment period

Study description

Background summary

There is an unmet medical need for long term treatments of endometriosis, in particular for treatments not impacting ovarian function and menstrual cycle. Based on results in animal experiments it is hypothesized than the AKR1C3 inhibitor BAY1128688 may offer relief from pelvic pain (a key symptom of patients with endometriosis) while not affecting ovarian function and menstrual cycle. Study 17472 is the first clinical investigation testing the hypothesis that administration of BAY1128688 translates into pain relief for patients with endometriosis. Study 17472 will also expand the data base regarding safety and tolerability of the AKR1C3 inhibitor BAY1128688.

Study objective

Purpose of the study is to test whether study drug BAY1128688 brings relief for pain to women with endometriosis and if so to get a first impression which dose(s) work best.

Study design

Randomized, placebo-controlled, double-blind, parallel-group, multi-center, exploratory dose-response study

V1: Screening visit: eDiary completion. Eligibility check based on VAS (4 week recall). First menstrual bleeding after V1. Screening period minimal 28 days and maximum of 105 days.
V2: Randomization visit. Phone call. Pre-treatment period maximum 45 days.
V3: start of treatment. Treatment period is 12 weeks.
V4: week 1-2
V5: week 4
V6: week 8
V7: week 12 = end of treatment.
V8: End of Study, safety follow up 42 days, 6 weeks.

Intervention

Study medication. BAY 1128688. Two tablets per day: 1 in the morning and 1 in the evening. There are 6 treatment arms.
3 mg, once daily + one placebo once daily
10 mg once daily + one placebo once daily
30 mg once daily + one placebo once daily
30 mg twice daily
60 mg twice daily

Reference drug: Placebo

Study burden and risks

Expected benefit: Health of participants will be monitored carefully. All study related visits to the study clinic and study assessments are free of charge. Benefit with regard to relief from administration of BAY1128688 is expected but uncertain. Risks: described in the patient information
Burden: The study consists of 7 site visits and one phone call visit. Visits comprise gynecological investigation and transvaginal ultrasound and blood drawings at each visit.
Participants will complete electronic hand held diary each day, during the whole duration of the study. Daily burden is estimated to be about 5 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Women of at least 18 years of age at the time of signing of informed consent.
- Women with endometriosis confirmed by at least one of the two criteria:
-- surgery within the last 10 years
-- imaging within the last 12 months
- moderate to severe pelvic pain which will be assessed over a period of 28 days
- Willingness to use only ibuprofen as rescue pain medication for endometriosis-associated pelvic pain.
- Willingness to use non-hormonal barrier method for contraception (here spermicide-coated condoms) from screening visit until the end of the study (unless adequate contraception is achieved by vasectomy of the partner or use of copper intrauterine device [IUD] or commitment to

abstinence) and to refrain from using hormonal contraception.

Exclusion criteria

- Pregnancy or lactation (more than three months since delivery, abortion, or lactation before start of treatment) AND no wish for pregnancy during the study.
- Altered bilirubin metabolism and liver function at Visit 1.
- Requirement to use pain medications for reasons other than endometriosis.
- Contraindications to using ibuprofen.
- Signs of hyperandrogenism.
- Absence of menstrual cycles and/or abnormal vaginal/genital bleeding
- History of hysterectomy, tubal-ligation or bilateral ovariectomy
- Uncontrolled thyroid disorder

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2018
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BAY1128688

Generic name:	BAY1128688

Ethics review

Approved WMO Date:	12-09-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-01-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-04-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-05-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-000244-18-NL
CCMO	NL62761.100.17

Study results

Results posted: 22-01-2020

Summary results
Trial ended prematurely

First publication
01-01-1900

URL result
Type
ext
Naam
www.clinicaltrialsregister.eu
URL