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Klimaktoplant H in patients with acute menopausal complaints

Submission date	Recruitment status	[ ] Prospectively registered
05/04/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/05/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/07/2017	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The menopause is when a woman stops having periods and is no longer able to get pregnant naturally. This is a natural part of the aging process that usually happens when a women is around 50 years old. At this time, a woman's oestrogen (female hormone) levels decline, leading to a range of symptoms, including hot flushes, sleep disturbances, and mood swings. There is a lot of evidence showing that the decline in oestrogen can be linked with an increased risk of heart disease and osteoporosis (brittle bones). One way of preventing this is by taking medication to replace the depleted osetrogen (hormone replacement), however this is unpopular. Klimaktoplant H is a medication used to treat menopausal symptoms without use of hormones. The aim of this study is to find out if taking Klimaktoplant H is an effective way of reducing menopausal symptoms.

Who can participate?
Women aged 40-55 years who are going through the menopause.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take two tablets containing Klimaktoplant H three times a day for 12 weeks. Those in the second group two tablets containing a placebo (dummy drug) three times a day for 12 weeks. Over the 12 weeks of the study, participants in both groups are regularly assessed in order to find out whether the Klimaktoplant H has had any effect on menopause symptoms.

What are the possible benefits and risks of participating?
Participants who are treated with Klimaktoplant H may benefit from a reduction in their menopausal symptoms. There is a risk for those taking Klimaktoplant H of side effects, such as allergic reactions, nosebleeds, and restarting menstrual bleeding.

Where is the study run from?
Six medical practices in Kiev (Ukraine)

When is the study starting and how long is it expected to run for?
December 2000 to January 2004

Who is funding the study?
Deutsche Homöopathie-Union (DHU)-Arzneimittel GmbH & Co. KG (Germany)

Who is the main contact?
Ms Julia Burkart

Contact information

Type(s)
Public

Contact name
Ms Julia Burkart

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Additional identifiers

Protocol serial number
KP 004

Study information

Scientific Title
Efficacy of Klimaktoplant H in patients with acute menopausal complaints

Study objectives
The aim of this study is to evaluate the efficacy and safety of Klimaktoplant H compared to placebo in patients with acute menopausal complaints.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the State Pharmacological Center of the Ministry of Health of Ukraine, 13/03/2001, ref: 5.12-91/KE

Primary study design
Interventional

Study design
Multi-centre prospective randomized double-blind placebo controlled phase III trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Acute menopausal complaints

Interventions
All patients meeting the entry criteria at baseline (day 0) are assigned to one of the two treatment sequences using a predetermined randomisation scheme.

Intervention group: Klimaktoplant H (Cimicifuga D2, Sepia D2, Sanguinaria D2, Ignatia D3) treatment starts immediately after the baseline visit (day 0) and continues for 12 weeks. Two tablets are taken orally three times a day. There is no run-in period, where patients are monitored before they receive Klimaktoplant H.

Control group: Placebo treatment startd immediately after the baseline visit (day 0) and continued for 12 weeks. Two tablets are taken orally three times a day. There is no run-in period, where patients are monitored before they receive Placebo.

All patients were followed for 12 weeks in total.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Klimaktoplant H

Primary outcome(s)
The efficacy of Klimaktoplant H compared to placebo, assessed as change of the total score of the Menopause Rating Scale, is measured using the Menopause Rating Scale at baseline (day 0) and 12 weeks (day 84).

Key secondary outcome(s)
1. Treatment outcome is measured using the Integrative Medicine Outcomes Scale (IMOS) at day 28, day 58 and day 84 rated by investigator and patients
2. Onset of the effect of investigational medication is measured by the entries in patient’s diary that is used during the treatment period
3. Health status of the patients is measured using the SF-12 Health Survey and EQ-5D questionnaire at baseline (day 0), day 28, day 58 and day 84
4. Satisfaction with treatment is measured using the Integrative Medicine Patient Satisfaction Scale (IMPSS) at day 84

Completion date
30/01/2004

Eligibility

Key inclusion criteria

1. Age 40–55 years
2. Acute menopausal complaints in the pre-, peri- and early postmenopausal period
3. Total score of the Menopause Rating Scale ≥ 20 points and at least severe complaints concerning the symptom "hot flushes, sweating"
4. Female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Menopause is longer than 3 years ago
2. Forced indication for hormonal replacement therapy (e.g. surgical menopause, manifest osteoporosis)
3. Hormonal replacement therapy in the last 6 months before enrolment into the trial and/or treatment with herbal or homeopathic medication in the last 3 months before enrolment into the trial
4. Concomitant medications, that might impair the trial result (e.g. hormones, centrally effective antihypertensive agents, other therapies of menopausal complaints)
5. Known or supposed hypersensitivity against trial medication
6. Severe concomitant diseases, e.g. heart and liver diseases, and/or immune suppression or multimorbidity
7. Known alcohol or drug abuse
8. Have taken part in another clinical trial during the last 6 months
9. Irresponsible patients or patients unable to understand nature, meaning and consequences of the trial

Date of first enrolment
24/04/2001

Date of final enrolment
26/11/2002

Locations

Countries of recruitment
Ukraine

Study participating centre
Faculty No 1 of Obestrics and Gynecology of the National Medical University A.A. Bogomolets
Shavchenko Avenue 17

Kiev
Ukraine
01004

Study participating centre
Pregnant consultation hour No 1 of the medical district area of Radianskiy region
Zoologicheskaya Street 3
Kiev
Ukraine
01004

Study participating centre
Pregnant consultation hour No 3 of the medical district area of Radianskiy region
Bogdana Khmelnitskogo Street 37
Kiev
Ukraine
01000

Study participating centre
Pregnant consultation hour No 1 of the medical district area of Leningradskiy region
Kuchera Street 7
Kiev
Ukraine
01000

Study participating centre
Pregnant consultation hour No 3 of the 1st adult polyclinic of the medical district area of Dneprovskiy region
Petra Zaporozhtsa 17
Kiev
Ukraine
01000

Study participating centre
Pregnant consultation hour for obestrics No 4 of the medical district of Minskiy region
Geroev Stalingrada 16
Kiev
Ukraine
01210

Sponsor information

Organisation
Deutsche Homöopathie-Union (DHU)-Arzneimittel GmbH & Co. KG

ROR
https://ror.org/0451ek747

Funder(s)

Funder type
Industry

Funder Name
Deutsche Homöopathie-Union (DHU)-Arzneimittel GmbH & Co. KG

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to ethical reasons, participant confidentiality and in terms of other data protection law.

IPD sharing plan summary
Not expected to be made available