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Efficacy and safety of lymphdiaral basistropfen in the treatment of chronic low-back pain

Submission date
18/05/2009

Recruitment status
No longer recruiting

Registration date
17/06/2009

Overall study status
Completed

Last Edited
16/04/2019

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01049373

Secondary identifying numbers
PSC 144/03

Study information

Scientific Title
Efficacy and safety of lymphdiaral basistropfen (a homoeopathic remedy [HDC]) in the treatment of chronic low-back pain considering consitution and diathesism: a double blind, randomised, placebo controlled, single-centre study

Study objectives
To evaluate superiority of HDC in comparison to placebo in the treatment of chronic low-back pain in relation to pain, functional impairment, quality of life, and state of health during a 15-week treatment period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bergmannsheil Bochum Ethikkommission, 23/07/2003

Study design
Interventional double-blind randomised placebo-controlled single-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Low-back pain

Interventions
Intervention: lymphdiaral basistropfen, a homoeopathic remedy of 12 drugs, oral solution
Control: placebo oral solution

Each is to be taken 3 times daily, 10 drops in some liquid over 15 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lymphdiaral basistropfen

Primary outcome measure
Change in FFbH-R following 15 weeks treatment

Secondary outcome measures
1. Change in FFbH-R following 2 weeks treatment
2. Change in pain score (SES) following 2 weeks treatment
3. Change in pain score (ES) following 15 weeks treatment
4. Change in strength of pain (Visual analog scale VAS) following 2 weeks treatment
5. Change in strength of pain (Visual analog scale VAS following 15 weeks treatment
6. Change in state of health (BF-S) following 2 weeks treatment
7. Change in state of health (BF-S) following 15 weeks treatment
8. Change in Oswestry Score following 2 weeks treatment
9. Change in Oswestry Score following 15 weeks treatment
10. Change in short form health survey 12 items (SF-12) following 2 weeks treatment
11. Change in short form health survey 12 items (SF-12) following 15 weeks treatment
12. Correlation of efficacy with the constitutional type of the patient, measured by the Hattinger Konstitutional Manual (HKM) and the Hattinger Konstitutional Questionnaire (HKF)
13. Amount of analgesics used
14. Number of days with incapability to work under 15 weeks treatment
15. Tolerability within 15 weeks treatment

Overall study start date
05/12/2003

Completion date
05/05/2007

Eligibility

Key inclusion criteria
1. Male and female patients
2. Aged 18 - 75 years
3. Chronic low-back pain lasting at least for 6 months
4. Hanover functional ability questionnaire (FFbH-R) score less than 70%
5. At least one of the following diagnoses:
5.1. Chronic lumbar ischialgia with or withour radicular radiation
5.2. Chronic degenerative lumbar syndrome
5.3. Spondylarthrosis
5.4. Chronic facette syndrome
5.5. Lumbage with protrusion of the intervertebral disc
5.6. Lumbar radiculopathia
5.7. Lumbar and other intervertebral disc impairments with radiculopathia
5.8. Back pain at different locations of the spine
6. Written, informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
140 (70 verum, 70 placebo)

Total final enrolment
137

Key exclusion criteria
1. Participation in another clinical trial/GCP-trial within 30 days prior to screening
2. Participation in this trial in an earlier time
3. Treatment with lymphdiaral basistropfen within 3 month prior to enrolment
4. Pregnancy and lactation
5. Non-compliance
6. Incapability to understand the sense of the study
7. Abuse of analgesics, opiates or other drugs
8. Chronic pain that are as strong as or even stronger than the pain caused by the low-back and that need to be treated with analgesics
9. Malign diseases
10. Pathological neurological states
11. Epilepsy
12. Operation of the spine within 3 month prior to enrolment
13. Fractures of the spine
14. Bechterew's disease
15. Alcohol abuse
16. Consuming diseases
17. Cachexia
18. Palsy of the legs or anal sphincter due to acute impairment of the intervertebral disc
19. Catheterisation or CT-controlled intra-articular injection in the lumbar region
20. Hypersensitivity against one of the ingredients or excipients of the study drugs or against composite plants in general
21. Systemic, progressive diseases like tuberculosis, leucosis, collagenosis, multiple sclerosis, acquired immune deficiency syndrome (AIDS), human immunodeficiency virus (HIV) infection, or other auto-immune diseases

Date of first enrolment
05/12/2003

Date of final enrolment
05/05/2007

Locations

Countries of recruitment
Germany

Study participating centre
Klinikum Blankenstein
Hattingen
Germany
D 45527

Sponsor information

Organisation
PASCOE pharmazeutische Praeparate GmbH (Germany)

Sponsor details
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Sponsor type
Industry

Website
http://www.pascoe-global.com

ROR
https://ror.org/02xbx2821

Funder(s)

Funder type
Industry

Funder Name
PASCOE pharmazeutische Praeparate GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Results article	results	28/06/2012	16/04/2019	Yes	No