

Protocol Registration Receipt
09/19/2011

Evaluation of Liposomal Curcumin in Healthy Volunteers

This study is currently recruiting participants.

Verified by Michael Wolzt, M.D., Medical University of Vienna, September 2011

Sponsor:	SignPath Pharma, Inc.
Collaborators:	
Information provided by (Responsible Party):	Michael Wolzt, M.D., Medical University of Vienna
ClinicalTrials.gov Identifier:	NCT01403545

► Purpose

Aim of the present study is:

- To evaluate the safety and tolerability of increasing doses of intravenous liposomal Curcumin in healthy subjects by means of adverse events, vital signs and safety laboratory assessments.
- To investigate the pharmacokinetics of increasing doses of intravenous liposomal Curcumin in healthy subjects.

Condition	Intervention	Phase
Drug Safety	Drug: Liposomal Curcumin Placebo	Phase 1

Study Type: Interventional

Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Caregiver, Investigator), Randomized, Safety Study

Official Title: Safety, Tolerability and Pharmacokinetics of Liposomal Curcumin in Healthy Volunteers - A Phase I Dose Escalation Study

Further study details as provided by Michael Wolzt, M.D., Medical University of Vienna:

Primary Outcome Measure:

- Safety and tolerability of increasing doses of intravenous liposomal Curcumin in healthy subjects by means of adverse events, vital signs and safety laboratory assessments. [Time Frame: From Baseline until 7 days after the study day] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Investigation of the pharmacokinetics of increasing doses of intravenous liposomal Curcumin in healthy subjects. [Time Frame: From Baseline until 48 hours after IMP administration] [Designated as safety issue: No]

Estimated Enrollment: 30

Study Start Date: August 2011

Estimated Study Completion Date: December 2011

Estimated Primary Completion Date: December 2011

Arms	Assigned Interventions
Experimental: Liposomal Curcumin Single dose, dose escalation	Drug: Liposomal Curcumin Single dose intravenous infusion of liposomal Curcumin at 10, 20, 40, 80, 120, 180 mg/m ² over 120 minutes
Placebo Comparator: 5% Glucose	Placebo 5% glucose infusion over 120 minutes

Eligibility

Ages Eligible for Study: 18 Years to 45 Years

Genders Eligible for Study: Both

Accepts healthy volunteers.

Inclusion Criteria:

- Healthy male and female subjects.
- Age between 18-45 years.
- Body mass index between 18-27 kg/m²
- Vital signs within the normal range after 5 minutes in supine position (SBP: ≥ 90 mmHg and ≤ 140 mmHg, DBP: ≥ 45 mmHg and ≤ 90 mmHg, Heart rate: ≥ 45 bpm and ≤ 90 bpm).
- Normal ECG (PR-interval ≤ 210 ms, QRS duration ≤ 140 ms, QTc ≤ 450 ms).
- Adequate bone marrow function as evidenced by an absolute neutrophil count ≥ 1500 cells/ μ l, all normal red blood cell indices, hemoglobin greater than 11 g/dl and a platelet count greater than 150,000/ μ l.
- Normal renal function.
- Normal hepatic function as evidenced by serum total bilirubin ≤ 1.2 mg/dl, or less than or equal to the upper

limit of normal, and alkaline phosphatase less than or equal to the upper limits of normal, and ASAT and ALAT less than or equal to the upper limits of normal.

- Normal coagulation profile, and activated partial thromboplastin time (aPTT).
- Normal urine analysis.
- Signed informed consent.

Exclusion Criteria:

- Intake of steroids within 2 weeks prior to the first dose of study drug.
- Concomitant medications (especially anticoagulants and aspirin) or herbal supplements.
- Active infection, or a fever > 38.5°C within three days prior to the first scheduled day of study drug dosing.
- Current or past history evidence of disease (e.g. hemolytic diathesis, anemia requiring substitution therapy, hemochromatosis) that could be exacerbated by administration of liposomal curcumin.
- History of prior malignancy within the past five years except for curatively treated non-melanoma skin cancer or cervical intraepithelial neoplasia.
- Allergy requiring medical treatment within the last four weeks.
- Known hypersensitivity to any of the components of turmeric.
- Participation in another clinical trial within 4 weeks before study initiation.
- NYHA Class 2 or congestive heart failure, uncontrolled hypertension, or arrhythmias.
- Positive HIV serology or evidence of active hepatitis.
- Unstable medical condition or any other medical condition, including mental illness or substance abuse, deemed by the investigator to be likely to interfere with the patient's ability to sign the informed consent form, or his ability to cooperate and participate in the study, or to interfere with the interpretation of the results.
- History of treated or active seizure disorder or any CNS or PNS neurological disorder.
- Subjects who are pregnant or breast feeding

Contacts and Locations

Contacts

Michael Wolzt, MD

0043-1-40400 Ext. 2981

michael.wolzt@meduniwien.ac.at

Locations

Austria

Medical University of Vienna, Department of Clinical Pharmacology Recruiting

Vienna, Vienna, Austria, 1090

Contact: Michael Wolzt, MD 0043-1-40400 Ext. 2981 michael.wolzt@meduniwien.ac.at

Principal Investigator: Michael Wolzt, MD

Sub-Investigator: Ghazaleh Gouya, MD

Sub-Investigator: Stefan Weisshaar, MD

Sub-Investigator: Jasmin Arrich, MD

Sub-Investigator: Beatrice Marzluf, MD

Investigators

Principal Investigator: Michael Wolzt, MD

Medical University of Vienna,
Department of Clinical

 More Information

Responsible Party: Michael Wolzt, M.D., Ao. Univ. Prof. Dr., Medical University of Vienna

Study ID Numbers: Lipocurc1001
2011-001861-41 [EudraCT Number]

Health Authority: Austria: Agency for Health and Food Safety (AGES)