Thrombocytopenia Induced by Chemotherapy (papayaleaf)

Glossary

Study record managers: refer to the Data Element Definitions if submitting registration or results information.

ClinicalTrials.gov Identifier: NCT03567798

Recruitment Status : Completed
First Posted : June 25, 2018

Last Update Posted : June 27, 2018

Sponsor:

Information provided by (Responsible Party):

Socrates School Of Health

Study Description
Go to
Brief Summary:

Single blind, randomized, multicentric placebo controlled study to evaluate the efficacy of Study product in patient with Chemotherapy induced thrombocytopenia. The Study is divided into [screening visit (visit 1) > baseline and treatment allocation visit (visit 2) >blood collection (visit 3); treatment compliance visit (visit 4) > blood collection (visit 5) >blood collection (visit 6)>end of study visit (visit 7)].

Condition or disease	Intervention/treatment	Phase
Thrombocytopenia	Dietary Supplement: UPLAT Other: Placebo	Not Applicable

Detailed Description:
UPLAT® (Carica papaya leaf Extract + Tinospora cardifolia Extract), is an orally administered dietary supplement for management of thrombocytopenia. Manufactured bySanat Products Ltd.

Throughout study, it will be designated as product A to maintain study blindness at subject end.

Placebo Throughout study, it will be designated as product B to maintain study blindness at subject end.

Single blind, randomized, multicentric placebo controlled study to evaluate the efficacy of Study product in patient with Chemotherapy induced thrombocytopenia. The Study is divided into [screening visit (visit 1) > baseline and treatment allocation visit (visit 2) >blood collection (visit 3); treatment compliance visit (visit 4) > blood collection (visit 5) >blood collection (visit 6)>end of study visit (visit 7)].

Dose regimen After meeting the inclusion criteria subject will take 4 units daily (2 in morning and 2 in evening) for 10 days. Patients will be called on Day5th, 10th and 15thfor the Complete blood count (Central lab).

Total blood loss Approximately 8-12 mL

Study Design
Go to

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	60 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	Single blind, randomized, multicentric placebo controlled study
Masking:	Single (Participant)
Masking Description:	Single Blind
Primary Purpose:	Treatment

Official Title:	A Post Marketing Randomized Placebo Controlled Study to Evaluate the Efficacy of Study Product UPLAT® (Carica Papaya Leaf Extract + Tinospora Cardifolia Extract) in the Cancer Patients With Thrombocytopenia Induced by Chemotherapy
Actual Study Start Date :	July 18, 2017
Actual Primary Completion Date :	November 20, 2017
Actual Study Completion Date :	November 20, 2017

Arms and Interventions
Go to

Arm	Intervention/treatment
Experimental: A UPLAT® (Carica papaya leaf Extract + Tinospora cardifolia Extract Take 4 units daily (2 in morning and 2 in evening) for 10 days	Dietary Supplement: UPLAT Carica papaya leaf Extract + Tinospora cardifolia Extract
Placebo Comparator: B Placebo Take 4 units daily (2 in morning and 2 in evening) for 10 days	Other: Placebo Placebo

Outcome Measures
Go to

Primary Outcome Measures :

1. Increase in the platelet counts from baseline levels to the end of therapy. [Time Frame: Day 15]
   Increase in the platelet counts from baseline levels to the end

   of therapy.

Eligibility Criteria
Go to

Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years to 55 Years (Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

1. Male or female aged between 18-55 years.
2. Subjects must sign with date an informed consent prior to any evaluation and participation in the trial.
3. Patients who were confirmed solid tumour and received at least one cycle of chemotherapy prior to screening visit.
4. Patients with a platelet counts between > 20000 and < 150,000/ml at the time of screening.

Exclusion Criteria:

1. Planning to receive any type of surgery.
2. Pregnant or lactating women.
3. Patients with platelet count less than 20000/ml.
4. Patients with thrombocytopenia presenting with active bleeding.
5. Patients who have received blood or blood product transfusion during the current illness or during past one week.
6. Patients with thrombocytopenia purpura (ITP) leukemia, hemophilia or bleeding diathesis.
7. Participation in another trial with another investigational product

Contacts and Locations
Go to

Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03567798***

Locations

India
North East Cancer Centre Hospital and research Institute
Guwahati, Assam, India, 781023

Sponsors and Collaborators

Socrates School Of Health

More Information

Go to

Responsible Party:	Socrates School Of Health
ClinicalTrials.gov Identifier:	NCT03567798 History of Changes
Other Study ID Numbers:	SPL/UP/2017/01
First Posted:	June 25, 2018 Key Record Dates
Last Update Posted:	June 27, 2018
Last Verified:	June 2018
Individual Participant Data (IPD) Sharing Statement:	
Plan to Share IPD:	Undecided
Plan Description:	Not Yet Decided

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

Thrombocytopenia
Blood Platelet Disorders
Hematologic Diseases

To Top