

Thrombocytopenia Induced by Chemotherapy (papayaleaf)

CT clinicaltrials.gov/ct2/show/NCT03567798

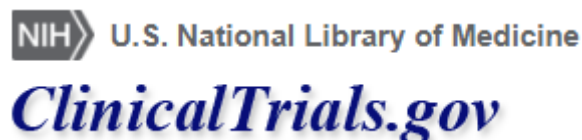
Glossary

Study record managers: refer to the [Data Element Definitions](#) if submitting registration or results information.

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Trial record **1 of 1** for: [uplat](#)

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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

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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 by Sanat 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 Day 5th, 10th and 15th for the Complete blood count (Central lab).

Total blood loss Approximately 8-12 mL

Study Design

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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

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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

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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

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Information from the National Library of Medicine

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

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Information from the National Library of Medicine

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

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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

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