ISRCTN16279156 https://doi.org/10.1186/ISRCTN16279156

Assessment of the anti-anaemic activity of a ready-to-serve beverage developed from sharbat-e-gudhal (a traditional hibiscus rosa-sinensis syrup) in comparison with traditional sharbat-e-gudhal and ferrous sulphate supplementation in patients with mild iron-deficiency anaemia

Submission date
03/07/2026

Recruitment status
Recruiting

Registration date
08/07/2026

Overall study status
Ongoing

Last Edited
15/09/2026

Condition category
Haematological Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Fathima Rizniya

ORCID ID
https://orcid.org/0009-0001-0963-2528

Contact details
No. 50 St. Lazarus Road, Periyamulla
Negombo
Sri Lanka
11500
+94 (0)773016949
rizniyamnf@fim.cmb.ac.lk

Type(s)
Scientific

Contact name
Prof Bernadene Fernandopulle

ORCID ID
https://orcid.org/0000-0002-0024-5054

Contact details
Department of Pathology, Faculty of Medical Sciences, University of Sri Jayewardenepura
Sri Jayewardenepura
Sri Lanka
10100
+94 (0)777746864
fernandopulle@sjp.ac.lk

Type(s)
Scientific

Contact name
Prof Pradeepa Jayawardane

ORCID ID
https://orcid.org/0009-0004-8937-1488

Contact details
Department of Pharmacology, University of Sri Jayewardenepura
Sri Jayewardenepura
Sri Lanka
10100
+94 (0)712304322
pradeepa@sjp.ac.lk

Type(s)
Scientific

Contact name
Prof Kamal Perera

ORCID ID
https://orcid.org/0000-0003-0337-1336

Contact details
Faculty of Indigenous Medicine, University of Colombo, Rajagiriya
Sri Jayewardanapura
Sri Lanka
10100
-
kamalperea@fim.cmb.ac.lk

Type(s)
Public, Scientific

Contact name
Dr Mohamed Mawjood

Contact details
Faculty of Indigenous Medicine, University of Colombo, Rajagiriya
Sri Jayewardanapura
Sri Lanka
10100
+94 (0)714422394
drmawjood@fim.cmb.ac.lk

Additional identifiers

Study information

Scientific Title
Efficacy and safety of a ready-to-serve beverage derived from sharbat-e-gudhal (a traditional syrup of China rose-unani formula used in faqrud dam [anemia]) in the management of mild iron-deficiency anaemia: a randomized controlled trial

Study objectives
To comparatively evaluate efficacy and safety of a ready-to-serve (RTS) beverage derived from sharbat e gudhal and sharbat e gudhal (the traditional syrup) with standard iron supplements in patients with mild iron deficiency anaemia.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/04/2026, Ethical Review Committee, Faculty of Indigenous Medicine (University of Colombo, Rajagiriya, Colombo, 10100, Sri Lanka; +94 (0)112692385; ethicsreview@fim.cmb.ac.lk), ref: ERC 24/265

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Anaemia

Interventions
Recruited patients will be asked to visit the clinic periodically as the instructions given by the principal investigator (3 weeks after the first visit, with completion of the first month and monthly thereafter). Participants will be assigned to test groups I and II and the control group as described below.
Group I: 150 ml of RTS beverage from sharbat-e-gudhal given at 10:00 am as a snack
Group II: Sharbat-e-gudhal given as 25 ml in the morning and 25 ml at night before meals
Control group: one tablet of ferrous sulphate (200 mg) with one tablet of vitamin C (100 mg) at night 2 hours before dinner

Randomization will be done using computer-generated random numbers that are obtained using Research Randomizer.

Duration of protocol therapy: 120 days

The patients will be assessed subjectively and by objective parameters on days 0 (baseline), 21, 90, and 120. On these days a questionnaire will be administered to them by the investigators to collect data on their views regarding the improvement of symptoms on treatment and to detect any adverse effects of the treatment. Further, a blood sample (5 ml) will be taken for the required analysis by a qualified phlebotomist (nurse/medical lab technician). The blood tests will be performed at an accredited laboratory

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
RTs beverage derived from sharbat-e-gudhal

Primary outcome(s)
1. Haemoglobin levels measured using fully automated haematology analyzer at baseline, 21st , 90th and 120th days

2. Serum ferritin levels measured using a specialized immunoassay analyzer at baseline and 120th day

Key secondary outcome(s)
1. Liver function (serum glutamic oxaloacetic transaminase [SGOT], serum glutamic-pyruvic transaminase [SGPT] and serum bilirubin levels) measured using the automated biochemistry analyzer at baseline, 21st, 90th and 120th days

2. Kidney function (serum creatinine levels) measured using the automated biochemistry analyzer at baseline, 21st, 90th and 120th days
3. Blood glucose control (glycated haemoglobin [HbA1c] levels) measured using the high-performance liquid chromatography (HPLC) at baseline and 90th day

Completion date
14/03/2028

Eligibility

Key inclusion criteria
1. Mild anaemic patients
2. Either sex
3. Aged 18 to 65 years
4. Patients with confirmed mild iron deficiency anaemia with the following limits:
4.1. Hb%: female: ≥9 g/dl and ≤12 g/dl; male: ≥9 g/dl and ≤13 g/dl
4.2. Serum ferritin: ≤30 µg/l

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients below 18 years and above 65 years of age
2. Moderate to severe anaemia (Hb%: ≤9 g/dl)
3. Patient with concurrent respiratory diseases, cardiovascular diseases, liver diseases and renal diseases
4. Pregnant and lactating women
5. Patients with a history of diabetes mellitus

Date of first enrolment
10/09/2026

Date of final enrolment
31/10/2027

Locations

Countries of recruitment
Sri Lanka

Study participating centre
National Ayurveda Hospital
National Ayurveda Hospital, Borella
Colombo
Sri Lanka

Sponsor information

Organisation
University of Sri Jayewardenepura

ROR
https://ror.org/02rm76t37

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr MNF Rizniya (rizniyamnf@fim.cmb.ac.lk). Study participant data sheets will not include contact or identifying details. Study data entry and study management systems used by clinical sites will be secured and password protected. At the end of the study, all study databases will be de-identified and archived. Availability of raw data of the study is based on the above conditions.

IPD sharing plan summary
Available on request