ISRCTN13257145 https://doi.org/10.1186/ISRCTN13257145

Mineralised drinking water to improve diabetes and high blood pressure control in Bangladesh

Submission date
05/12/2025

Recruitment status
Recruiting

Registration date
22/12/2025

Overall study status
Ongoing

Last Edited
19/12/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Diabetes and high blood pressure are two major health problems in Bangladesh, and many adults struggle to keep these conditions under control despite using medicines. Some minerals, such as magnesium, zinc, chromium, potassium and selenium, may help improve blood sugar and blood pressure. Aeon HD® mineralised water contains a balanced combination of these minerals.

This study aims to find out whether drinking this mineralised water every day for 12 weeks can help improve blood sugar levels and blood pressure in adults with uncontrolled type 2 diabetes and hypertension, compared with drinking normal water.

Who can participate?
Adults aged 30–60 years who have type 2 diabetes that is not well controlled, high blood pressure that is not well controlled, and have been taking the same diabetes and blood-pressure medicines for at least 60 days. People who are pregnant, severely ill, planning to move away from Dhaka, or unable to participate safely will not be included.

What does the study involve?
Participants will be randomly assigned to one of two groups. The intervention group will drink Aeon HD® mineralised water (one 200 mL glass, three times per day). The control group will drink the same amount of normal filtered water. The study lasts 12 weeks. At the beginning and end of the study, participants will have blood tests (HbA1c, fasting glucose, cholesterol, kidney and liver tests) and measurements of blood pressure and body size (weight, BMI, waist and hip). Participants will also have one mid-study check at week 6 to review progress and any side effects.

What are the possible benefits and risks of participating?
Benefits: Participants may experience improvements in blood sugar or blood pressure. They will receive regular health check-ups and laboratory assessments at no cost.
Risks: Mild stomach discomfort could occur due to mineral content in the water, although such reactions are expected to be uncommon. Any side effects will be monitored by a study doctor who is available 24 hours for support.

Where is the study run from?
The study is being conducted at the Diabetic Association of Bangladesh (BADAS) Outpatient Diabetes Centre in Dhaka.

When is the study starting and how long is it expected to run for?
The study will begin in November 2025 and is expected to run for approximately 7 months, including preparation, participant recruitment, the 12-week intervention period, data analysis, and reporting.

Who is funding the study?
The study is funded by the Diabetic Association of Bangladesh (BADAS), with technical collaboration from the Centre for Global Health Research (CGHR) and Aquanimity Bangladesh Limited.

Who is the main contact?
Professor Dr Bishwajit Bhowmik
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Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Evaluation of Aeon HD® mineralised water for improving diabetes and hypertension control in Bangladesh

Acronym
AQUA-DHC

Study objectives
Primary objective:
To evaluate the efficacy of SuperWater® enriched with Aeon HD® in improving glycaemic control among patients with uncontrolled type 2 diabetes and hypertension.

Secondary objectives:
1. To assess the effects of SuperWater® on blood pressure.
2. To assess the effects of SuperWater® on anthropometric measures (weight, body mass index, waist and hip circumference).
3. To evaluate changes in lipid profile, including total cholesterol, triglycerides, HDL-C, and LDL-C.
4. To examine changes in liver (SGPT) and renal function (serum creatinine).
5. To explore the safety and tolerability of daily consumption of SuperWater over 12 weeks.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/11/2025, Ethics Review Committee of Diabetic Association of Bangladesh (BADAS) (122 Kazi Nazrul Islam Avenue, Shahbag, 1000, Bangladesh; +880 (0)1819287912; info@dab-bd.org; shakil480@gmail.com), ref: BADAS-ERC/EC 125162

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Placebo

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
1. Aged 30–60 years
2. Diagnosed with uncontrolled or poorly controlled type 2 diabetes (HbA1c >8.0%, or fasting plasma glucose ≥10 mmol/L, or 2-hour post-breakfast glucose ≥12 mmol/L)
3. Diagnosed with uncontrolled hypertension (SBP >140 mmHg or DBP >90 mmHg)
4. On stable oral anti-diabetic and anti-hypertensive therapy for at least 60 days prior to enrolment
5. Willing and able to provide informed consent

Interventions
Intervention group: SuperWater® enriched with Aeon HD® (zinc sulfate heptahydrate, chromium picolinate, magnesium sulfate, vanadium (IV) oxide sulfate hydrate, potassium sulfate, sodium selenate); 200 ml, three times daily for 12 weeks.

Control group: Equivalent volume of normal filtered water.

Adherence will be monitored through weekly contact and consumption logs.

Participants will be randomly allocated in a 1:1 ratio to the intervention or control group using a computer-generated randomisation list created by an independent statistician who is not involved in participant recruitment or assessment. Randomisation will be performed using permuted block randomisation with variable block sizes of 4 and 6 to ensure balanced allocation throughout enrolment. The randomisation list will be stored in a password-protected file accessible only to the data manager.
Sequentially numbered, sealed, opaque envelopes (SNOSE) will be used to conceal allocation at the time of enrolment. After baseline data collection, the research coordinator will open the next envelope in sequence to assign the participant to their group.
Participants will remain blinded to group allocation; however, due to the nature of the intervention, investigators responsible for distribution of water cannot be blinded. Outcome assessors and laboratory staff will remain blinded to treatment assignment.

Intervention Type
Supplement

Primary outcome(s)
1. HbA1c (%) measured using laboratory HPLC assay at baseline and 3 months

2. Systolic and diastolic blood pressure (mmHg) measured using automated digital sphygmomanometer following WHO STEPS protocol (average of last two readings) at baseline and 3 months

Key secondary outcome(s))
Measured at baseline and 3 months:
1. Fasting plasma glucose (mmol/L) measured using enzymatic laboratory assay after 8–12 hours fasting
2. Lipid profile (TC, LDL-C, HDL-C, TG; mmol/L) measured using automated biochemistry analyzer using enzymatic colorimetric methods
3. Serum creatinine (mg/dL or µmol/L) measured using laboratory kinetic Jaffe or enzymatic assay
4. SGPT/ALT (U/L) measured using biochemistry analyzer using kinetic UV method
5. Proportion achieving glycaemic control (HbA1c < 7%) derived from lab-measured HbA1c
6. Proportion achieving blood pressure control (<140/90 mmHg) derived from automated BP readings
7. Body weight and BMI (kg, kg/m²) measured using digital scale, stadiometer; BMI calculated as kg/m²
8. Daily water intake (liters/day) measured using structured hydration questionnaire and intake log
9. Adverse events measured using structured adverse event reporting form reviewed at follow-up

Completion date
05/06/2026

Eligibility

Key inclusion criteria
Diabetes and hypertension

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 years

Upper age limit
60 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Decline participation or fail to provide consent
2. Pregnant or lactating women, or planning pregnancy during the study
3. Acute renal failure, liver disease, or severe metabolic disorder
4. Insulin use for >1 week before enrolment
5. Major surgery, acute infection, or pancreatitis within the last 3 months
6. Mental health conditions limiting participation
7. Not residing in Dhaka during the study period
8. Normotensive or untreated hypertensive individuals

Date of first enrolment
14/11/2025

Date of final enrolment
21/02/2026

Locations

Countries of recruitment
Bangladesh

Sponsor information

Organisation
Aquanimity Bangladesh Ltd

Funder(s)

Funder type

Funder Name
Centre for Global Health Research BADAS

Results and Publications

Individual participant data (IPD) sharing plan
De-identified individual participant data (IPD) will be shared with qualified researchers upon reasonable request. Interested investigators may email the Principal Investigator with a short proposal and data-use plan. After approval, data will be shared through a secure, password-protected digital platform. All recipients must sign a Data Access Agreement confirming that data will be used only for the approved purpose, not re-identified, and not shared further. A data dictionary will be provided.

IPD sharing plan summary
Available on request