

Press Release

Hyflux signs agreement with Changi General Hospital to conduct first human clinical trials of ELO Water on diabetes

Trials will study effects of ELO Water on diabetes control and diabetic foot ulcers

SINGAPORE, 15 February 2017 – Hyflux Ltd (Hyflux) today signed an agreement with Changi General Hospital (CGH) to conduct two clinical trials to establish the effectiveness of Hyflux's ELO Water and ELO Gel on diabetes control and diabetic foot ulcer patients.

The trials will study whether patients with diabetes can obtain better glycaemic control by drinking ELO Water in addition to their ongoing lifestyle and medical treatments, and whether diabetic foot or ankle ulcers can be treated with ELO Water bath and ELO Gel. Dr Joan Khoo, Senior Consultant and Chief of Endocrinology at CGH, is the principal investigator of both trials. Please refer to Annex 1 for details of the trials' study protocols.

Hyflux is committing up to S\$2.5 million in cash and in kind to human clinical trials to further ascertain the scientific merits of ELO Water. ELO Water is created through technology that allows a high level of oxygen to exist in the water in a unique, stable and bound form that is believed to allow quick absorption by the body, restoring its natural balance and enhancing health and overall well-being.

Positive results have been obtained from animal trials of ELO Water conducted overseas. Trials conducted by researchers at Monash University in Australia on transplanted human cancerous tumours in mice showed that ELO Water through oral application was able to be absorbed and penetrated into the tumours, enhancing oxygen levels inside the cancers and inhibiting their growth.

“We have made steady progress in introducing ELO to the wellness market. The partnership between Hyflux and CGH represents our commitment to further ascertain the scientific merits and efficacy of ELO Water and ELO gel on diabetes care. If the trials are successful, it will ultimately improve the quality of life for diabetic patients,” said Ms Olivia Lum, Executive Chairman and Group Chief Executive Officer, Hyflux.

“Diabetes is a significant public health concern for Singapore. Hyflux has come to us with an interesting hypothesis based on animal studies that could help our patients with diabetes. We have thus embarked on this research collaboration to test this hypothesis in a robust scientific way. This collaboration is part of CGH's commitment to innovation in healthcare. said Dr Lee Chien Earn, Chief Executive Officer, CGH.

In 2015, International Diabetes Federation reported that 12.8% or 541,600 of Singaporeans aged 20 years to 79 years were reported to have diabetes. The prevalence of Type 2 diabetes in Singapore is forecast to double from 7.3 per cent in 1990 to 15 per cent in 2050.¹

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About Hyflux

Hyflux is a global leader in sustainable solutions, focusing on the areas of water and energy. Headquartered and listed in Singapore, the Group has operations and projects in Southeast Asia, China, India, the Middle East, Africa and the Americas. Hyflux is committed to providing cost-effective and innovative solutions that contribute to resource optimisation and sustainable growth for communities and industries. A specialist in water treatment, Hyflux is distinctive in its ability to address the challenges at every point of the entire water value chain. The Group's track record includes Singapore's first water recycling plant and some of the world's largest seawater reverse osmosis desalination plants in Algeria, China and Singapore.

For more information, please visit www.hyflux.com

About Changi General Hospital

Changi General Hospital (CGH) is an award-winning public hospital with over 1000 beds serving a community of 1.4 million people in eastern Singapore. CGH offers a comprehensive range of medical specialties and services, helmed by a highly experienced and skilled team of healthcare professionals who consistently deliver excellent health outcomes and care for patients. CGH has been JCI (Joint Commission International) accredited since 2005.

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¹ Phan TP, Alkema L, et al. Forecasting the burden of type 2 diabetes in Singapore using a demographic epidemiological model of Singapore. *BMJ Open Diabetes Research and Care* vol. 2 issue 1. Available from: <http://drc.bmj.com/content/2/1/e000012> [Last accessed: 8 Feb 2017]

ANNEX A: STUDY PROTOCOLS

Study #1: A Double-Blinded Randomized Controlled Trial of ELO Water in Diabetes Care for Enhancement of Blood Sugar Control (EDEN Study)

Overview

This trial will evaluate the efficacy of ELO water as an additional treatment to enhance glycaemic control in patients with Type 2 diabetes

Rationale

Diabetes patients have been shown to have 10-15% lower tissue oxygenation (hypoxia), which is associated with higher insulin resistance. Tissue hypoxia also results in higher levels of long chain acyl-carnitines (LCAC), a by-product due to incomplete β -oxidation of fatty acids, which causes insulin signalling interference and affects insulin resistance. Reversing tissue hypoxia could lower insulin resistance.

Hypothesis

ELO water as an additional lifestyle intervention in Type 2 diabetes can improve glycaemic control.

Target outcome

Reduction in HbA1c of at least 0.5% in 24 weeks

Profile of study subjects

- 150 Type 2 diabetic patients
- 21 to 70 years old
- HbA1c between 8% and 11% inclusive in the last 6 months

Study design

- Two study groups
 - One group that drinks ELO water (n=75)
 - One control group that drinks placebo drinking water (n=75)
- Double blind, randomised controlled trial
 - Subjects will be randomly assigned to each study group
 - Subjects will not know which water they are drinking
 - Investigators will not know which water each patient is drinking
- Subjects will drink 1.5 litres* of ELO or drinking water daily in divided doses in addition to other fluids (1.5 litres is 50-75% of an adult’s recommended daily intake)
- They will keep a water consumption diary to monitor their intake

Trial schedule

Week	0	6	12	24
Consent taking	√			
Inclusion and exclusion criteria check	√			
CGH clinic review	√	√	√	√
Blood pressure	√	√	√	√
Height and weight	√	√	√	√
Blood and urine tests	√	√	√	√
Completion of study				√

Study #2: A Randomized Controlled Pilot Study to Assess the Effects of Using ELO Water and ELO Gel on Wound Healing for Diabetic Foot and/or Ankle Ulcers

Overview

This trial will assess the effects of a wound care regime using ELO water on wound healing for diabetic foot and/or ankle ulcers

Rationale

One of the complications of diabetes is the development of poorly healing chronic foot and/or ankle ulcers. Many diabetes patients undergo amputation for gangrene and infections that start from a non-healing ulcer. Diabetics have 10-15% lower tissue oxygenation than people without diabetes. Lower oxygenation (hypoxia) contributes to slow healing of ulcers and makes them more susceptible to infection. Enhancing tissue oxygenation promotes healing, inhibits infections, and improves the effect of antibiotics.

Hypothesis

Enhanced tissue oxygenation of diabetic foot and/or ankle ulcers through a wound care regime with ELO water can accelerate wound healing by increasing energy metabolism, and improving collagen synthesis as well as antimicrobial action.

Target outcome

Complete skin closure of ulcer at 3 weeks, 6 weeks, 9 weeks, and 12 weeks

Profile of study subjects

- 30 Type 2 diabetes patients
- 21 to 70 years
- Uncomplicated ulcer on the foot and/or ankle and/or ankle ulcer(s) with surface area of 7cm² to 20cm² inclusive
- HbA1c ranging between 7% to 10% inclusive within the last 4 months

Study design

- Baseline blood tests and measurement of ulcer area will be done using the iPhone LesionMeter app at CGH podiatry clinic
- Subjects in ELO treatment arms will undergo wound care by a nurse at Hyflux Innovation Centre or CGH
- Subjects given standard care will go for wound care at CGH
- During each wound care session, subjects will have their wound examined, photographed, and treated according to the allocated study intervention
- Patients in all 3 arms will be issued ELO water or drinking water (1.5 litres daily in divided doses) based on which group they have been allocated to
- They are allowed to drink other fluids
- They will also monitor their blood glucose twice daily
- An independent assessor who is blinded to the treatment allocation will perform final analysis of wound photographs for study outcomes

Trial schedule

Week	0	1	2	3	4	5	6	7	8	9	10	11	12
Consent taking	√												
Inclusion and exclusion criteria check	√												
Doctor clinic review		√											
Blood pressure, height/weight, blood/urine tests		√											
Baseline wound assessment and photography with LesionMeter app	√												
Wound care		Daily for ELO treatment arms. Standard wound care reviewed at frequency determined by attending podiatrist.											
Wound photography by LesionMeter app and review of wound photos by podiatrist		Twice a week											
Podiatry review for ELO treatment arms (A and C)	√		√		√		√		√		√		√
Podiatry review for standard treatment arm (B)	√	Discretionary according to podiatrist evaluation of the wound											
ELO bath	14 day bath/ 14 day break throughout the 12 weeks or until complete skin closure												
Self-monitored blood glucose	Twice daily – fasting and bedtime												
Completion of study													√