Clinical validation of miniature wearable dialysis machine

Objective

The project aims to validate a miniature wearable dialysis machine in a clinical setting and to prepare the system for CE-marking. Wearable dialysis allows renal patients to dialyze conveniently and continuously at home or at work, independently from a fixed water supply, up to 24 hrs/day. Such a continuous treatment mimics healthy kidneys and is twice as effective as current dialysis techniques, hereby offering health benefits, quality of life (fitness, mobility) while reducing medical costs (less medication, dialysis at home lowers costs). The miniature wearable dialysis system is based on continuous flow peritoneal dialysis with a fluidic access to the abdomen. The peritoneal dialysate is continuously circulated and refreshed by means of a small and wearable sorption unit that removes toxins from the dialysate. The technology has been demonstrated in preclinical research. In order to demonstrate the clinical efficacy and safety of the system an early feasibility first-in-human trial (phase 0) and a pilot crossover trial (phase 1) will be performed in peritoneal dialysis (PD) patients. The phase 0 study will involve a selected group of 12 stable PD patients in a clinical setting for 5 consecutive days. Upon successful functionality and safety analysis of the phase 0 trial, the clinical validation is continued in a crossover study to test the hypotheses that the system (1) improves blood purification, (2) results in adequate ultrafiltration and (3) does not show important safety/biocompatibility problems. Hereto 30 stable PD patients will be randomised to receive either with the wearable system in the first month and conventional PD in the second month or vice versa. The clinical trials will be performed by three European medical centres specialised in dialysis treatment.

Field of Science

/medical and health sciences/basic medicine/pharmacology and pharmacy/pharmaceutical drug

/medical and health sciences/clinical medicine/nephrology/renal dialysis
Programme(s)
H2020-EU.3.1.3. - Treating and managing disease

Topic(s)
SC1-PM-09-2016 - New therapies for chronic diseases

Call for proposal
H2020-SC1-2016-RTD

See other projects for this call

Funding Scheme
RIA - Research and Innovation action

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Activity type
Higher or Secondary Education Establishments

EU Contribution
€ 1 168 125

Website
Contact the organisation

Participants (3)
UNIVERSITA DEGLI STUDI DI MODENA E REGGIO EMILIA
Italy

Activity type
Higher or Secondary Education Establishments

EU Contribution
€ 597 250

Website
Contact the organisation
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<td>NANODIALYSIS BV</td>
<td>Netherlands</td>
<td>€ 984 750</td>
<td>De Korenaar 83 5688rx Oirschot</td>
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<td>Spain</td>
<td>€ 556 625</td>
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