# Optimized convective volumes in postdilution HDF using ULTRACONTROL - Effect on blood purification efficacy

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The study objectives are1. to compare blood purification efficacy for postdilution HDF treatment in ULTRACONTROL mode to that of i) postdilution HDF using volume control mode, and ii) high-flux HD treatment, using in all treatments the same dialyzer...

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Nephropathies |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON30377

**Source**
ToetsingOnline

**Brief title**
ULTRACONTROL HDF study

### Condition

- Nephropathies

**Synonym**
chronic kidney disease, hemodialysis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Gambro Lundia AB
**Source(s) of monetary or material Support:** de firma Gambro Lundia AB,Gambro Lundia AB

## Intervention

**Keyword:** AK 200 ULTRA S, convective therapy, Hemodiafiltration (HDF), ULTRACONTROL

## Outcome measures

### Primary outcome

The primary endpoint of the randomized, cross-over comparison between treatment modes is the pre- to post-dialysis reduction in plasma b2-microglobulin level

### Secondary outcome

2. As secondary endpoints, the following indices of treatment efficacy will be used

a. blood urea reduction from pre- to post-dialysis

b. Diascan Kt/V using Watson V as input

c. phosphate reduction from blood levels pre- and post-dialysis

d. uric acid reduction from blood levels pre- and post-dialysis

e. CRP reduction from blood levels pre- and post-dialysis

f. removal of complement factor D, based on changes in plasma level from pre- to post-dialysis

g. removal of cystatin C, based on changes in plasma level from pre- to post-dialysis

h. b2m, cystatin C, and factor D mass in spent dialysate

i. albumin mass in spent dialysate

# Study description

### Background summary

Hemodiafiltration (HDF) is a dialysis mode that effectively combines diffusive and convective transport and thus, in comparison with HD, offers conditions for enhanced removal of a wide range of uremic solutes. The greatest effect is on the removal of large solutes, often referred to as middle molecules. The AK 200 ULTRA S on-line system by Gambro has been widely used for such HDF treatments since 2001.
The most effective blood purification in HDF, i.e. the greatest clearance, is achieved in postdilution mode [Ledebo, 1999]. Here ultrafiltration is applied on undiluted blood and the substitution fluid is infused after the filter.
Theory predicts that the greater the exchange of fluid the higher the clearance [Waniewski 1991, Sternby 2005]. Clinical experience confirms that a greater volume in HDF is associated with greater removal of small solutes like urea and phosphate as well as of middle-sized solutes like b2m [Lornoy 2000, Lin 2001]. Additionally, a lower mortality risk has been observed in patients regularly treated with HDF with high exchange volumes [Canaud, 2006].
Conventionally, a postdilution HDF treatment is run in volume control, meaning that a target infusion volume (VINF) is set at treatment start. However, trans-membrane pressure (TMP) problems often arise during the course of HDF treatments in volume control mode, as levels of blood cells and proteins increase and make the filtration of plasma water more difficult. As a result, infusion volumes are typically set in the low range of what is expected as achievable to avoid such TMP alarms towards treatment end.
An alternative way to control HDF treatments when using the AK 200 ULTRA S system is to set a certain TMP to be kept throughout the treatment. This mode, using manual setting of the TMP value and referred to as Pressure Control Mode, allows for greater infusion volumes to be reached than in conventional HDF with volume control [Frouget, 2005].
Recently a new ULTRACONTROL feature has been developed and incorporated in the software 8.11 version for the AK 200 ULTRA S dialysis monitor. The ULTRACONTROL feature automatically finds the optimal TMP value to use in controlling the infusion rate during the HDF treatment. The ULTRACONTROL mode is therefore expected to make postdilution HDF treatments easier to prescribe and run, and to deliver infusion volumes at level or better with the best achieved using the current pressure control mode with manual TMP setting. Initial evaluations of software 8.11 in dialysis clinics in Sweden, Germany, and France have confirmed its effectiveness and ease of use.

**Study objective**

The study objectives are
1. to compare blood purification efficacy for postdilution HDF treatment in ULTRACONTROL mode to that of i) postdilution HDF using volume control mode, and ii) high-flux HD treatment, using in all treatments the same dialyzer, the same blood flow rate, and the same total dialysis fluid flow rate.
2. to evaluate in ULTRACONTROL HDF treatments the achieved convective volume (=infusion volume + UFV) and its intra- and inter-individual variation.

### Study design

Patients will be given one treatment of each of the following treatment modes, in randomized order, during which blood purification efficacy will be extensively evaluated from blood and dialysate samples (only mid-week; week 2-4):
• Postdilution HDF using ULTRACONTROL
• Postdilution HDF using conventional Volume Control mode
• High-flux HD
In addition (week 1; all treatments and week 2-4; treatments 1 and 3 only) nine postdilution HDF treatments using ULTRACONTROL will be evaluated on the delivered convective volume in relation to other treatment parameters. No blood or dialysate samples will be collected for these treatments.
Blood flow rates and dialysis flow rates will be kept constant during the 4 study weeks.
Fluid removal according to each patient*s current needs

### Intervention

The intervention in this study consists out of the randomisation of the three dialysis modalities (A) post-dilution HDF with ULTRACONTROL; (B) post-dilution HDF with volume control and (C) standard high-flux hemodialysis. This randomisation will only be carried out for the second treatment of week 2 to week 4. For all other treatments (all treatments of week 1 and treatment 1 and 3 of week 2 to 4) only routine postdilution HDF with ULTRACONTROL treatments will be done assessing the convective volume. Blood and spent dialysate samples will only be taken during the random treatments A, B and C.

### Study burden and risks

There is no extra burden to patients related to the study apart from:
• Being informed about the study and signing informed consent
• Blood loss of maximum 60 ml blood in 3 weeks time

This study fits well in current routine dialysis treatment of our current patients. No additional risks are foreseen. Some patients for which HDF is prescribed may feel less comfort during 1 out of 12 treatments when randomised to standard high-flux HD but since this treatment is mid-week this risk is low.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1 on dialysis since 3 months or longer
2 stable on on-line postdilution HDF therapy since at least 1 month
2a of which at least one week in ULTRACONTROL mode using Polyflux H dialyzer
2b known on what total UF rate in relation to QB is possible during volume control mode when Polyflux H dialyzer is used, without having monitor TMP alarms
3 regularly achieving a blood flow rate of 250 ml/min or more
4 giving written consent to participate

## Exclusion criteria

1 Age <18 years
2 Dialysis schedule other than 3 treatments per week
3 Treatment time <3* or >5 hours
4 Showing unstable blood flow rates and/or regularly showing access recirculation exceeding 5%.
5 Treatments in single needle mode

6 Expected to show poor compliance to dialysis prescription
7 Known HIV, HBV, or HCV infection
8 Known coagulation disorder
9 Pregnant women, nursing mothers and women planning a pregnancy during the course of the study
10 Patients under guardianship
11 Participation in other studies that could interfere with the objectives of this study

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-12-2006 |
| Enrollment: | 10 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Generic name: | a new software version on an existing dialysis monitor |
| Registration: | Yes - CE intended use |

# Ethics review

Approved WMO

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| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
| --- | --- |
| CCMO | NL15285.058.06 |