

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

**Problems of care of elderly insulin-dependent diabetics in general practice - testing a standardised information system between general practices and care workers (BAIDIA II)**

### Trial Acronym

**BAIDIA II**

### URL of the trial

<http://web.uk-halle.de/index.php?id=5127>

### Brief Summary in Lay Language

**The BAIDIA I enquiry showed that between general practitioners, medical assistants and care workers remarkable mutual information deficits prevail in view of therapy aims, therapy instructions (e.g. insulin schemes and insulin doses), therapy follow-up, report intervals and indications for mutual sharing of information as well as home visits.**

**A format for a systematic ensuring of understanding as well as a covering of therapy aims respectively power to act is needed.**

**Such a format for a standardised exchange of information could be (with a positive evaluation and broader implementation) a relevant indicator for remuneration of structural quality in selective or collective treatment contracts between general practitioners, care workers and medical insurance companies in the future.**

**Therefore the pilot study BAIDIA II not only foculises on clinical relevant endpoints of diabetis bt also on the improvement of actual treatment reality older type 2 diabetics, inter-professional approach to therapy options and in view of interverntion on the communicative transfer of therapy management (doctor) to realised therapy and its possible complications (care).**

### Brief Summary in Scientific Language

**The prevalence of diabetes mellitus rises up to 20 percent in the age group of over 70 years old besides a demographic dependent proportion of geriatric patients at the general medical care.**

**While an intensive and complex diabetes therapy for non-geriatric patients is more beneficial for morbidity processes, an intensified diabetes therapy for geriatric patients is valued more often as complicated and since the ACCORD study more and more reluctant.**

**With the discussion about an adequate diabetes therapy for geriatric patients comes the question, how demands on an autonomous cooperation of this patient group can be realised, to the fore.**

**Since the insulin utilization and the daily dealing with the disease (diet, dining intervals etc.) ist not only ensured by the patients itself but by fostering people from domestic environment or professional care workers.**

**Guidelines for diagnostic and therapy of diabetes can not unconditional be transferred on the observed geriatric clientele but require transmission into individualised guidance for patients and their fostering relatives resp. care workers.**

**The BAIDIA I study revealed, with the help of interviews with general practitioners, their medical assistants and professional care workers, mutual coordination- and information-needs between the involved occupational groups. Especially care workers required appropriate insulin therapy-schemes with information about measurement-dependent dose-correction, general practitioners required prompt information about diabetes lapses and care- resp. supply-problems.**

**Therefore focuses the submitted follow-up study BAIDIA II on an enhancement of supply reality of older type 2 diabetics by the use of a standardised fax-based communication tool between care workers and general practitioners.**

**Do you plan to share individual participant data with other researchers?**

[---]\*

**Description IPD sharing plan**

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00006081**
- Date of Registration in DRKS: **2015/01/13**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2014-94 , Ethikkommission der Medizinischen Fakultät der Martin-Luther-Universität Halle Wittenberg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **E10 - Insulin-dependent diabetes mellitus**
- ICD10: **E11 - Non-insulin-dependent diabetes mellitus**

## Interventions/Observational Groups



- **Arm 1: Implementation of a standardised bilateral information system between family practices and care attendants (and vice versa) as an one-sided facsimile template (obligation of nonproliferation of the template).**  
**At the beginning of the study-implementation (t0) a product-neutral advanced training course, concerning insulin management and diabetes, will take place with at least 8 family practices.**
- **Arm 2: Implementation of an identic advanced training course concerning insulin management without the facsimile template at at least 8 family practices.**  
**Practices in the control group receive coded documentation templates and furthermore a facsimile template which informs the care attendants about the study in general, announces both an endpoint elicitation and patients' satisfaction questionnaire and urges alternating communication ("placebo" facsimile template).**  
**Cooperating care facilities/nursing services will be gathered and excluded if necessary in order to minimize contamination of the study arms by intergroup contact care attendants.**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: **patient/subject**
- Control: **Placebo**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Amount of reported blood sugar lapses (< 4 or > 20 mmol/l [ $< 72$  or  $> 360$  mg/dl]) from care attendants to general practitioner at the time of 3 and 6 month after intervention (t1 + t2).**

## Secondary Outcome

**Amount of planned/unplanned home visits by general practitioners and/or medical assistants**

**Amonut of diabetes caused hospital and/or specialist treatment (t0 + t1 + t2)**

**HbA1c values (t0 + t1 + t2)**

**Patients-/(relatives-) satisfaction (EUROPEP questionnaire) ( only t2)**

**Evaluation of quality of communication, patients safty and work simplification of**



**the information system by general practitioners, medical assistants and care workers (only t2)**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- Doctor's Practice **Halle (Saale) und Umgebung**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/11/15**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **65 Years**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**Age > 65 years**  
**insulin-dependent diabetes mellitus type 1 and 2 (every kind of insulin regime**  
**blood sugar controls at least once a week)**  
**being under general practitioner's care and care attendants' care**  
**(ambulant/stationary)**

### Exclusion criteria

**Age ≤ 65 years**  
**diabetes mellitus without insulin therapy or with blood sugar controls less than**  
**once a week**  
**being under non-professionals' care (e.g. relatives)**  
**unfavourable primary diseases with a life expectancy less than 6 months**  
**risk of contamination by congruent identities of professional care attendants**  
**(nursing services, nursing homes) in intervention and control group**  
**denial of disclosure of secondary data by the principal investigator**

**Age ≤ 65 years**

**diabetes mellitus without insulin therapy or with blood sugar controls less than once a week**

**being under non-professionals' care (e.g. relatives)**

**unfavourable primary diseases with a life expectancy less than 6 months**

**risk of contamination by congruent identities of professional care attendants (nursing services, nursing homes) in intervention and control group**

**denial of disclosure of secondary data by the principal investigator**

## Addresses

### ■ Primary Sponsor

**Dekan der Medizinischen Fakultät der Martin-Luther-Universität Halle-Wittenberg**

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### ■ Contact for Scientific Queries

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### Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

**Kassenärztliche Vereinigung Sachsen-Anhalt  
Doctor-Eisenbart-Ring 2  
39120 Magdeburg  
Germany**

Telephone: **(0391)6276000**

Fax: **(0391)6278999**

E-mail: [---]\*

URL: **<http://www.kvsa.de>**

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

**Sanofi-Aventis Deutschland GmbH  
Industriepark Höchst, K703  
65926 Frankfurt am Main  
Germany**

Telephone: **0180/2222010**

Fax: **0180/2222011**

E-mail: [---]\*

URL: **<http://www.sanofi.de>**

- **Private sponsorship (foundations, study societies, etc.)**

**Hausärzteverband Schsen-Anhalt e.V.  
Margaretenstraße 2  
39218 Schönebeck  
Germany**

DRKS-ID: **DRKS00006081**

Date of Registration in DRKS: **2015/01/13**

Date of Registration in Partner Registry or other Primary Registry: [---]\*

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**Private sponsorship (foundations, study societies, etc.)**

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URL: **<http://www.hausaerzteverband-sachsen-anhalt.de/>**

## Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]\*

## Trial Publications, Results and other documents

\* This entry means the parameter is not applicable or has not been set.

\*\*\* This entry means that data is not displayed due to insufficient data privacy clearing.