Evaluation of the Accu-Chek® Combo System by subjects treated with CSII (Continuous Subcutaneous Insulin Infusion).

Published: 30-11-2008
Last updated: 06-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON33856

Source
ToetsingOnline

Brief title
Combo study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, Diabetes Mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Disetronic Medical System AG
Source(s) of monetary or material Support: Disetronic Medical System

Intervention

Keyword: CSII, glucose meter, insuline pump, remote control feature

Outcome measures

Primary outcome

End point data for this study will be obtained from the following sources:

1: From pump downloads:

2: From meter downloads:

3: From Diary

4 :From Questionnaires

Secondary outcome

Not Applicable.

Study description

Background summary

Background:
Insulin pump therapy has become a well established therapy for persons with diabetes mellitus.
Disetronic Medical Systems AG (DMS) has created Accu-Chek® Combo which consists of an insulin pump (Accu-Chek® Spirit Combo) and a multifunctional blood glucose meter (Accu-Chek® Aviva Combo) containing an optional remote control for the insulin pump.
Accu-Chek® Spirit Combo distinguishes itself from its predecessor, the Accu-Chek® Spirit, through the addition of two new features. First, the Accu-Chek® Spirit Combo pump can be remote controlled by Accu-Chek® Aviva Combo, and second it contains an additional occlusion detection algorithm designed to detect potential occlusions earlier.
Accu-Chek® Aviva Combo is a blood glucose meter containing an electronic diary,

the insulin pump remote control and a bolus calculator.
Meal and correction boluses can be calculated based on a current blood glucose value, planned carbohydrate intake and health status using the patients therapy parameters stored in the device. The calculated bolus can be modified by the patient or delivered directly by transmitting it to the insulin pump. Using the display of the Accu-Chek® Aviva Combo various other tasks can be performed on the pump e.g. programming a Temporary Basal Rates, allowing more discrete operation of the pump.

Study objective

The primary objective is to measure the frequency of unexpected critical errors* of the Accu-Chek Combo® encountered during everyday normal use.
(*Unexpected critical errors are device related events that may result in an adverse or serious adverse patient event or device event and have a novel fault description not yet found in the product risk analysis or that occur with a higher frequency than estimated in the product risk analysis and result in a change in the risk assessment.)

The secundary objectives are:
• To document the frequency of all system errors, for example, the functionality of the new occlusion detection system, the communication system and the data management system. Frequency will be evaluated by reviewing data downloaded from the meter and pump.
• To document the usage of system functionalities. Frequency of reports will be used for blood glucose meter and frequency of events for the pump
• Collect clinical data on frequency with which the bolus calculator is used, adjustment of the proposed bolus amounts by the patient and the impact of bolus calculator (BC) use on metabolic control.
- Frequency of use of bolus calculator (calculated from meter history downloads)
- Patients' adjustment of the proposed bolus amounts (differences between the calculated bolus amounts and the ones delivered) will be calculated from meter downloads and analyzed depending on blood glucose (BG) levels and bolus intention (food intake, correction bolus)
- Impact of bolus calculator use on metabolic control: Correlation between BC use and the change of metabolic control (7-point BG profiles, HbA1c) from baseline to study end
• Evaluate change in subjects* satisfaction with diabetes treatment using Diabetes Treatment Satisfaction Questionnaire (DTSQs / DTSQc)
• Evaluate the subjects* CSII training, handling perception/feature satisfaction & preferences of Accu-Chek® Combo System using Perception Questionnaires
• Obtain feedback on used training materials using the Training Evaluation Form
• Collect routine clinic data on metabolic status using HbA1c values

Study design

A multi-center, prospective, controlled unblinded, single group study.
5-8 sites in the Netherlands and UK.
Total of 93 patients.
total duration of treatment is 26 weeks.

Intervention

In this study the following assessments / evaluations should be done:
- 4 time bloodcollection for HbA1c measurement.
- collection of 2 urine samples.
- subject should answer 6 questionnaires.
- daily completion of diary.
- daily self management of blood glucose (4 times per day).
- during 3 days before each visit daily self management of blood glucose (7 times per day).

Study burden and risks

Burden:
They ask the subjects to visit the hospital 4 times within 26 months, to come to a training session and to follow a computer training. There will be one consult by telephone.

They ask the subjects to complete 6 questionnaires, to complete a diary with important events (battery change, error messages, health complains and problem with pump and/or remote controle.

They will take 4 x 5 ml blood for HbA1c control.
They will take 2 urine samples for glucose and proteine determination

The subjects are willing to perform self management of blood glucose at least 4 times per day and during the 3 days before each visit 7 times per day.

The risks and disadvantages are very similar to those the subject experiences with his/her current pump.
During the course of this study, there is a possibility that the patient may experience the following side effects or discomforts:
• possible hyperglycemia / hypoglycemia (unusually high or low blood glucose levels)
• skin irritation, pain, infections, at the site of the infusion pump
• anxiety laboratory test results
• mild discomfort and soreness or infection from multiple finger sticks
• anxiety over recording blood glucose values that maybe unfamiliar to you.

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

• Subjects must be 18 years or older at the time of the screening visit
• Subjects must have an HbA1c <=10% (taken less than 3 months before the screening visit)
• Subjects must be willing to perform self management of blood glucose (SMBG) at least 4 times per day
• Willing to perform episodic monitoring prior to study visits (3 days x 7 BG-tests)
• Subjects must currently be using an insulin pump for at least 6 months prior to the screening visit
• Subjects are willing to use the bolus calculator and remote control features of the system
• Subjects should be willing to adhere to the study visit schedule

Exclusion criteria

• Subjects who used systemic oral or inhaled steroids for > 14 days within the last 3 months
• Subjects on Chemotherapy or Radiation therapy (self-reported)
• Subjects currently addicted to alcohol or substances of abuse as determined by the investigator
• Subjects planning to relocate or travel extensively (for periods of more than 2 weeks during phase I of the study
• Subjects with psychological issues which would impair ability to consent or participate (at the Physicians* discretion)
• Subjects show have had severe hypoglycemia requiring 3rd party assistance within the last 4 weeks
• Subjects who are either pregnant or lactating or are currently planning a pregnancy

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-12-2008
Enrollment:	65
Type:	Actual

Medical products/devices used

Generic name:	insulin pump (Accu-Chek® Spirit Combo) with an additional remote control feature (Accu-Chek® Aviva C
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-11-2008
Application type:	First submission
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)
Approved WMO Date:	06-02-2009
Application type:	Amendment
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)

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	NL25468.003.08