KH Donauspital

Abteilung f. Anästhesie und Intensivmedizin A- 1220 Wien, Langobardenstraße 122 Prof.Dr. Walter Klimscha	Intraoperative Anästhesie Dokumentaiton 03.06.2011 vidiert

Patient:	ALLINGER PAUL
Gebdat.:	20.11.2006
Pat.AZ:	unbekannt
SV-Nr.:	201106

EINGRIFF
Anlage/Wechsel PEG Sonde

DIAGNOSE
Epilepsie

PATIENTEN DATEN

Alter:	4 J.	Größe:		Liegestation:	44	OP-Gruppe:	OP Gruppe 1
Blutgruppe:		Gewicht:	16 kg	Priorität:	geplant	OP-Saal:	Z-OP-09
ASA:	3	NYHA:		OP-Fach:	Chirurgie	Entlassen nach:	

PERSONAL
Dokumentation vidiert durch: Pabisch Dr. Sabine
Anästhesist Pabisch Dr. Sabine ✓ Operateur Pomberger Gerhard, Dr. ✓

ALLERGIEN

INTRAOP. MEDIKAMENTE TOTAL
Fentanyl 50 µg/ml inj 20 µg
Propofol 1% 80 mg

INTRAOP. FLÜSSIGKEIT TOTAL
Elomel isoton, 288 ml, i.v. inf, Gestartet:03.06.11 08:24, Beendet:03.06.11 09:18

.ITMARKEN

Patient im OP:	08:18	Schnitt:	08:48
Anästhesie ...	08:18	Naht:	09:00
Anästhesie Fertig:	08:29	Extubation:	09:12
Intubation:	08:28	Anästhesie Ende:	09:18
		Patient aus OP:	09:18

ANÄSTHESIE DAUER: 1 h
EINGRIFF DAUER: 12 min

BILANZ

	EINFUHR:	AUSFUHR:	BILANZ:
BLUT intraop.:			
FLK intraop.:	296 ml		296 ml
TOTAL intraop.	296 ml		296 ml

PRIMÄRE TECHNIK: Allgemeinanästhesie
SEKUNDÄRE TECHNIK:

ANÄSTHESIEN
Endotracheal-Tubus Heidleberg Mikrocuff 5 Tubus mit Cuff: Ja Cuffdruck
Monitoring ✓ Schwierige Intubation: Nein

LOKAL & REGIONAL

ZUGÄNGE - TUBEN - DRAINAGEN
Zugang bereits vorhanden: ✓ i.v.-KatheterEllenbeugeRechts 22G blau 0,8x25mm

ANDERE EREIGNISSE

MONITORING - AUSSTATTUNG
08:40 warmes Tuch ✓
08:40 SpO2 Messung: Finger
08:40 NIBD Messung: Linker Arm
08:40 EKG Ableitung: 3 pol. EKG

ANÄSTHESIE PFLEGE CODES
7.15.0. Gastroskopie/ Ösophagusbougierung/ PEG-Sonde

LAGERUNGEN
08:38 Rückenlage
? Nacken normal

PATIENTENSCHUTZ
08:41 Druckstellen ✓
08:41 Augenschutz: Beide
08:41 Kopfpolster ✓
08:41 Hals in Neutralposition ✓
08:41 Position Rechter Arm: angelegt
08:41 Kein Druck auf Augen ✓
08:41 Position Linker Arm: ausgelagert
08:41 Arme unterpolstert: Beide
08:41 Beine unterpolster: Beide
08:41 Augenschutz ✓
08:41 Zugängliche Arme: Linker Arm

NOTIZEN

ANWEISUNGEN

POSTOP. ANWEISUNGEN STATION

Infusionstherapie: ELOMEL isoton i.v. 64ml/h
Monitoring: SaO2 Monitoring
Sauerstoffgabe: O2-Insufflation mit 3 l/min
Schmerztherapie: Perfalgan i.v. 240mg, max. 4xtäglich

03.06.11 08:45 Pabisch Dr. Sabine

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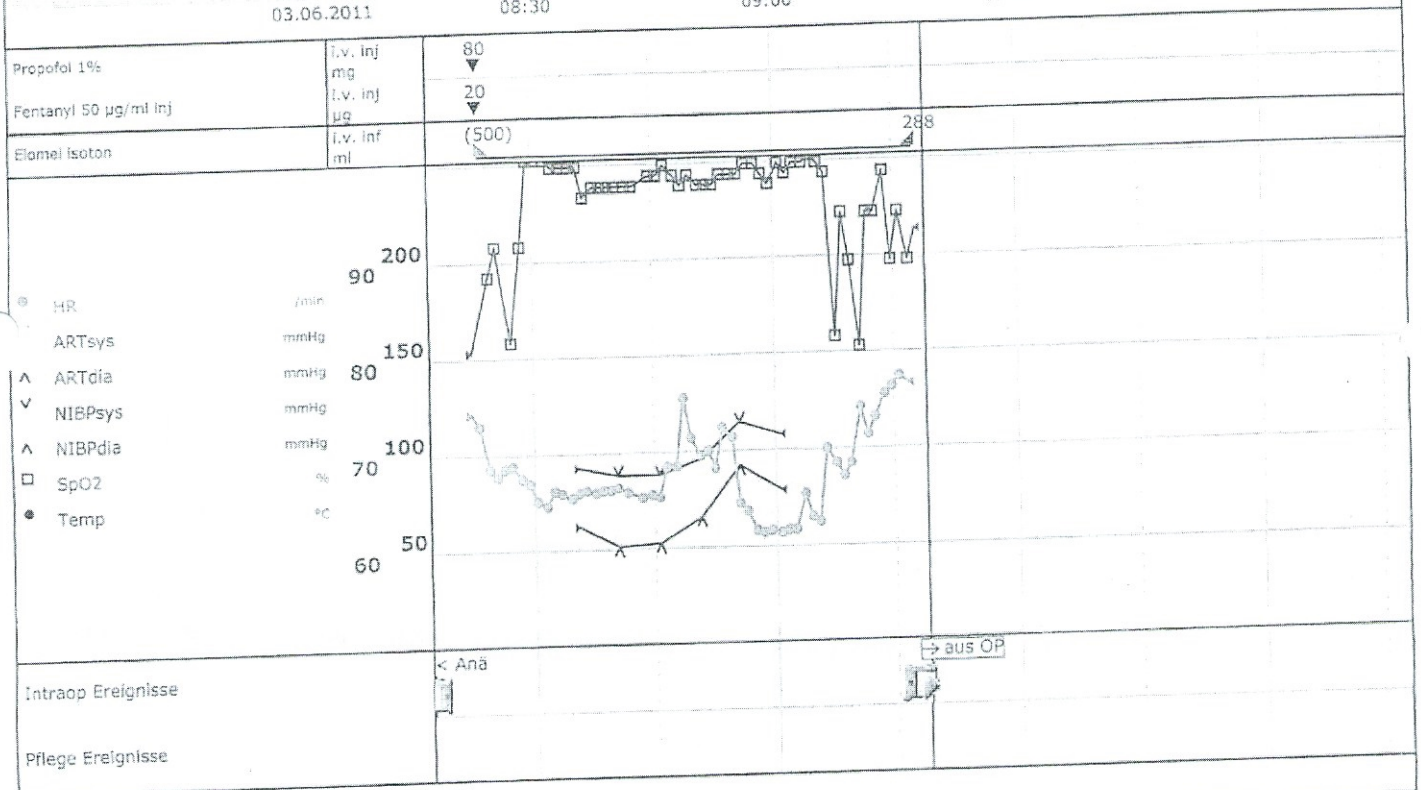
BEHANDLUNGSDATEN



ARTEFAKTE

Zeit	Art	Grund	Kommentar

KH Donauspital

Abteilung f. Anästhesie und Intensivmedizin

A- 1220 Wien, Langobardenstraße 122
Prof.Dr. Walter Klimscha

Intraoperative Anästhesie Dokumentaiton
03.06.2011
vidiert

Patient:	ALLINGER PAUL
Gebdat.:	20.11.2006
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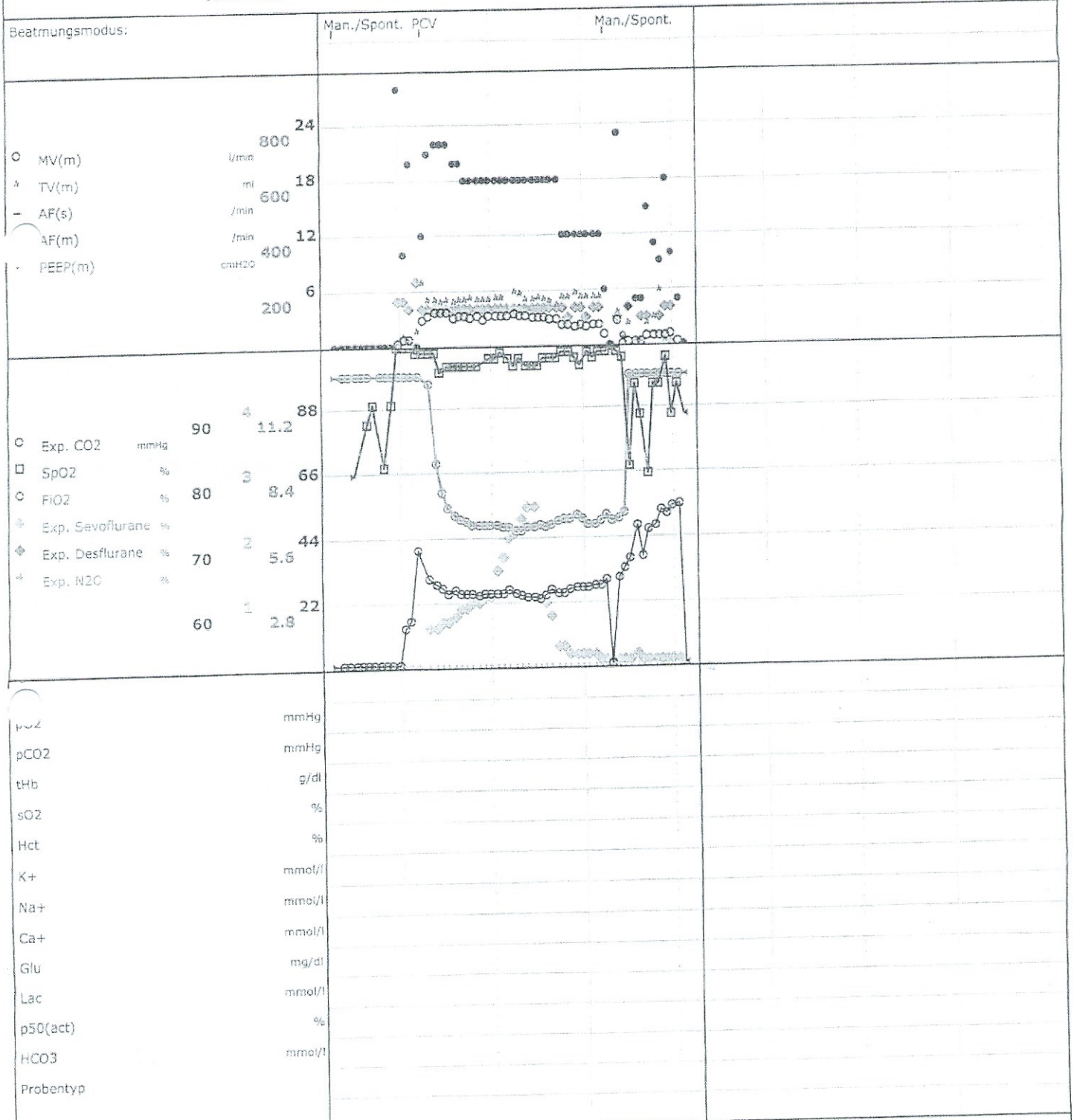
NARKOSEMASCHINE / BLUTGASDATEN



pO2	mmHg
pCO2	mmHg
tHb	g/dl
sO2	%
Hct	%
K+	mmol/l
Na+	mmol/l
Ca+	mmol/l
Glu	mg/dl
Lac	mmol/l
p50(act)	%
HCO3	mmol/l
Probentyp	

A Study to Investigate the Efficacy and Safety of Cannabidiol (GWP42003-P; CBD) as Adjunctive Treatment for Seizures Associated With Lennox-Gastaut Syndrome in Children and Adults

This study is not yet open for participant recruitment. (see Contacts and Locations)

Verified August 2014 by GW Research Ltd

Sponsor:
GW Research Ltd

Information provided by (Responsible Party):
GW Research Ltd

ClinicalTrials.gov Identifier:
NCT02224560

First received: August 21, 2014
Last updated: August 22, 2014
Last verified: August 2014
History of Changes

Purpose

To investigate the potential antiepileptic effects of cannabidiol (GWP42003-P) in subjects with Lennox-Gastaut syndrome.

Condition	Intervention	Phase
Epilepsy Lennox-Gastaut Syndrome	Drug: GWP42003-P Drug: Placebo control	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Randomized, Double-blind, Placebo-controlled Study to Investigate the Efficacy and Safety of Cannabidiol (GWP42003-P; CBD) as Adjunctive Treatment for Seizures Associated With Lennox-Gastaut Syndrome in Children and Adults.

esource links provided by NLM:

Genetics Home Reference related topics: CASK-related intellectual disability Lennox-Gastaut syndrome pyridoxal 5'-phosphate-dependent epilepsy

MedlinePlus related topics: Epilepsy Seizures

Genetic and Rare Diseases Information Center resources: Lennox-Gastaut Syndrome

U.S. FDA Resources

Further study details as provided by GW Research Ltd:

Primary Outcome Measures:

- Mean percentage change from baseline in number of drop seizures (average per week) during the maintenance period. [Time Frame: 2-14 weeks] [Designated as safety issue: Yes]

  The primary endpoint is the mean percentage change from baseline in number of drop seizures (average per week) during the maintenance period (Day 15 to the end of the evaluable period) in subjects taking GWP42003-P compared with placebo.

Secondary Outcome Measures:

- Mean percentage change from baseline in number of drop seizures (average per week) during the Weeks 1-4, 5-8 and 9-12 of the maintenance period. [Time Frame: 2-14 weeks] [Designated as safety issue: Yes]

- Number of subjects considered treatment responders, defined as those with a ≥25%, ≥50%, ≥75%, or 100% reduction in drop seizures from baseline. Summaries will be presented overall and four-weekly. [Time Frame: 2-14 weeks] [Designated as safety issue: No]
- Number of subjects experiencing a >25% worsening, −25 to +25% no change, 25-50% improvement, 50-75% improvement or >75% improvement in drop seizures from baseline. [Time Frame: 2-14 weeks] [Designated as safety issue: Yes]
- Mean percentage change from baseline in number of non-drop seizures (average per week). [Time Frame: 2-14 weeks] [Designated as safety issue: Yes]
- Mean percentage change from baseline in the frequencies of sub-types of seizures (average per week). [Time Frame: 2-14 weeks] [Designated as safety issue: Yes]
- Mean change from baseline in Quality of Life. [Time Frame: 2-14 weeks] [Designated as safety issue: No]
- Changes from baseline in the Caregiver Global Impression of Change (CGIC) score. [Time Frame: 2-14 weeks] [Designated as safety issue: No]
- The incidence of adverse events as measure of subject safety. [Time Frame: Day -28 to Day 137] [Designated as safety issue: Yes]
- The number of age-appropriate subjects with a treatment-emergent flag using the Columbia-Suicide Severity Rating Scale (C-SSRS or C-SSRS Children's depending on age) during the course of the study. [Time Frame: Day -28 to Day 137] [Designated as safety issue: Yes]

Estimated Enrollment:	120
Study Start Date:	January 2015
Estimated Study Completion Date:	December 2015
Estimated Primary Completion Date:	December 2015 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: High Dose Level GWP42003-P	Drug: GWP42003-P Other Names: • Cannabidiol • CBD • Epidiolex
Experimental: Low Dose Level GWP42003-P	Drug: GWP42003-P Other Names: • Cannabidiol • CBD • Epidiolex
Placebo Comparator: Placebo Control	Drug: Placebo control Other Name: Placebo

Detailed Description:
This study is a 1:1:1 randomized, double-blind, 14-week comparison of two Dose Levels of GWP42003-P versus placebo. The treatment period will consist of a two-week titration period followed by a 12-week maintenance period. The study will aim to determine the efficacy, safety and tolerability ;WP42003-P compared with placebo. The High Dose Level will be as recommended by the Data Safety Monitoring Committee (DSMC) after assessment of safety and pharmacokinetic data from Part A of study GWEP1332. The Low Dose Level will be defined as 50% of the High Dose Level. The first subject will not enroll into this study until the DSMC has reviewed the safety data from Part A of study GWEP1332.

Following study completion, all subjects will be invited to continue to receive GWP42003-P in an open label extension (OLE) study (under a separate protocol).

Eligibility

Ages Eligible for Study:	2 Years to 55 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria
Key Inclusion Criteria:

- Subject must be male or female aged between two and 55 years (inclusive).
- Subject must have a documented history of Lennox-Gastaut syndrome. This includes written documentation of having met electroencephalogram (EEG) diagnostic criteria during the patient's history and evidence of at least one type of generalized seizure, including drop seizures (atonic, tonic, tonic-clonic or myoclonic) for at least six months.
- Subjects who have a history of slow (<2.5 Hz) spike-and-wave pattern in an EEG prior to the enrollment into the baseline period.
- Subjects must have at least two drop seizures each week during the 28-day baseline period.
- Subjects should be refractory; that is having documented failures on more than one antiepileptic drug (AED).
- Subject must be taking one or more AEDs at a dose which has been stable for at least four weeks prior to screening.

- All medications or interventions for epilepsy (including ketogenic diet and vagus nerve stimulation [VNS]) must have been stable for four weeks prior to screening and patient is willing to maintain a stable regimen throughout the study. The ketogenic diet and VNS treatments are not accounted as an AED.

Key Exclusion Criteria:

- Etiology of subject's seizures is a progressive neurologic disease. Subjects with tuberous sclerosis will not be excluded from study participation, unless there is a progressive tumor.
- Subject has had an anoxic episode requiring resuscitation within six months of screening.
- Subject has clinically significant unstable medical conditions other than epilepsy.
- Subject has had clinically relevant symptoms or a clinically significant illness in the four weeks prior to screening or randomization, other than epilepsy.
- Subject is currently using or has in the past used recreational or medicinal cannabis, or synthetic cannabinoid based medications (including Sativex®) within the three months prior to study entry and is unwilling to abstain for the duration of the study.
- Subject has any known or suspected hypersensitivity to cannabinoids or any of the excipients of the Investigational Medicinal Product (IMP), such as sesame oil.
- Subject has been part of a clinical trial involving another IMP in the previous six months.
- Subject has significantly impaired hepatic function at screening (Visit 1) or randomization (Visit 2) (Alanine aminotransferase [ALT] >5 x upper limit of normal [ULN] or total bilirubin [TBL] >2 x ULN) OR the ALT or Aspartate aminotransferase (AST) >3 x ULN and (TBL >2 x ULN or international normalized ratio >1.5). This criterion can only be confirmed once the laboratory results are available; subjects randomized into the study who are later found not to meet this criterion should be withdrawn from the study.
- Any history of suicidal behavior or any suicidal ideation of type four or five on the Columbia Suicide Severity Rating Scale in the last month or at screening.
- Subject is taking more than four concurrent AEDs.
- Subject has taken corticotropins in the six months prior to screening.
- Subject is currently taking long-term systemic steroids (excluding inhaled medication for asthma treatment) or any other daily medication known to exacerbate epilepsy. An exception will be made of prophylactic medication, for example, idiopathic nephrotic syndrome or asthma.
- Subject is taking felbamate, and they have been taking it for less than one year prior to screening.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02224560

Contacts

Contact: Richard Potts +44 (0) 1980 557000 rp@gwpharm.com

Sponsors and Collaborators

GW Research Ltd

More Information

No publications provided

Responsible Party:	GW Research Ltd
ClinicalTrials.gov Identifier:	NCT02224560 History of Changes
Other Study ID Numbers:	GWEP1414, 2014-002940-42
Study First Received:	August 21, 2014
Last Updated:	August 22, 2014
Health Authority:	United States: Food and Drug Administration

Keywords provided by GW Research Ltd:
Cannabidiol
CBD
Epidiolex
GWP42003-P

Additional relevant MeSH terms:
Epilepsy
Epilepsy, Generalized
Intellectual Disability
Spasms, Infantile
Brain Diseases
Nervous System Diseases
Neurobehavioral Manifestations
Neurologic Manifestations
Signs and Symptoms
Mental Disorders Diagnosed in Childhood