KURZPROTOKOLL
LEO AK 0041

Öffentlicher Titel	Phase IV Studie zu Ingenolmebutat-Gel vs Diclofenac-Natrium-Gel bei aktinischer Keratose im Gesicht oder auf der Kopfhaut
Wissenschaftl. Titel	Efficacy and safety of ingenol mebutate gel 0.015% compared to diclofenac sodium gel 3% in subjects with actinic keratoses on the face or scalp
Kurztitel	LEO AK 0041
Studienart	multizentrisch, prospektiv, randomisiert, zweiarmig, einfach verblindet
Studienphase	Phase IV
Erkrankung	Haut: Hautkrebs: Aktinische Keratose
Ziele	- To compare the efficacy of daily application for 3 consecutive days of ingenol mebutate gel 0.015% with the efficacy of diclofenac sodium gel 3% for 90 days in subjects with AK on the face or scalp.
Einschlusskriterien	- Following verbal and written information about the trial, subject must provide informed consent documented by signing the Informed Consent Form (ICF) prior to any trial related procedures - Subjects with 4 to 8 clinically typical, visible and discrete AKs within a contiguous 25 cm^2 treatment area on the face or scalp - Subject at least 18 years of age - Female subjects of childbearing potential must be confirmed not pregnant by a negative urine pregnancy test prior to trial treatment and must be willing to use effective contraception at trial entry and until completion.
Ausschlusskriterien	- Location of the selected treatment area: - a.on the periorbital skin - b.on the perioral skin/around the nostrils - c.within 5 cm of an incompletely healed wound - d.within 10 cm of a suspected BCC or SCC or other neoplasia - Selected treatment area lesions that have atypical clinical appearance (e.g., hypertrophic, hyperkeratotic or cutaneous horn) or recalcitrant disease (e.g., did not respond to AK treatment in the previous) - History of SCC, BCC, malignant melanoma or other neoplasia in the selected treatment area - History or evidence of skin conditions other than the trial indication that would interfere with evaluation of the trial medication in the selected treatment area (e.g., eczema, unstable psoriasis, xeroderma pigmentosum) - Use of ingenol mebutate and/or diclofenac sodium in and within 5 cm of the selected treatment area within the last 12 months prior to Visit 1 - Use of cosmetic or therapeutic products and procedures which could interfere with the assessments of the treatment area - Known or suspected hypersensitivity or allergy to any of the ingredients in ingenol mebutate gel or diclofenac sodium gel - Organ transplant recipients - Immunosuppressed subjects (for example HIV patients) - Clinical diagnosis/history or evidence of any medical condition that would expose a subject to an undue risk of a significant AE or interfere with assessments of safety and efficacy during the course of the trial, as determined by the investigator’s clinical judgment - Presence of acute sunburn within the selected treatment area - Current enrolment or participation in a clinical trial within 30 days of entry into this trial - Female subjects who are breastfeeding

	- Subjects who are institutionalized by court order or by the local authority - In the opinion of the investigator, the subject is unlikely to comply with the Clinical Study Protocol (e.g. alcoholism, drug dependency or psychotic state)
Alter	18 Jahre und älter
Fallzahl	500
Sponsor	Eli Lilly and Company Leo Pharma GmbH
Förderer	Eli Lilly and Company
Registrierung in anderen Studienregistern	EudraCT 2014-003218-98
Therapie	Therapy with Ingenol mebutate gel 0.015%