AdisInsight: Trials



AdisInsight: Trials (öceki adıyla Adis Clinical Trials Insight) hem uluslararası hem de gözlemsel araştırmaları kapsayan önde gelen derinlemesine ve güncel klinik araştırma verileri kaynağıdır. Uluslararası düzenleyici yollarla ticari gelişimdeki ilaçları ilerletmek için yapılan temel klinik araştırmaları hızla tanımlanmasına yardımcı olur.

İçerikte:

- Phase of trial and current status
- Trial purpose, focus and design
- · Primary and other endpoints
- Diseases and subjects treated
- Inclusion and exclusion criteria
- Trial identifiers
- Organizations involved

- Initiation, completion and end dates
- Interventions
- · Study center and investigator details
- Trial history
- Outcomes and results
- Related authors

Uluslararası biyomedikal dergi ve konferanslardan alınan önemli makalelerin son derece yapılandırılmış değerlendirmeleri aşağıdaki alanlarda klinik verileri ve denemeleri kapsar:

Affective Disorders

Alzheimer's, Cognition Disorders

Antibacterials Antithrombotics Antivirals

Anxiety Disorders

Arrhythmias

Cancer Chemotherapy Cardiovascular Disorders Congenital Disorders

Connective Tissue Disorders

Diabetes

Digestive System Disorders Ear, Nose and Throat Disorders

Endocrine Disorders

Epilepsy and Seizure Disorders

Eye Disorders

Genitourinary Disorders

Haematological Disorders Heart Failure

Hyperlipidaemia Hypertension

Immunological Disorders

Inflammation

Irritable Bowel Syndrome

Ischaemic Heart Disease

Liver Disorders Men's Health Metabolic Disorders Mouth Disorders

Musculoskeletal Disorders

Mycoses

Nausea & Migraine Neurological Disorders **Nutritional Disorders**

Obesity

Obstructive Airways Disease

Pain Control
Parasitic Infections
Parkinson's Disease
Peptic Ulcer Disease
Psychotic Disorders

Respiratory Tract Disorders

Rheumatic Disease Skin Disorders

Thrombosis and Embolism

Transplant Rejection

Vaccines

Vascular Disorders Viral Infections Women's Health

Tarih Kapsamı 1990–günümüze

Kapsam

Uluslararası

Güncelleme Sıklığı

Haftalık

Doküman Türü

Tam Metin Adis değerlendirmeleri

SAMPLE DOCUMENT: ONGOING TRIAL



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TI

A Phase 2b Randomized, Double-Blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Preterm Infants

PUB, PD, YR

AdisInsight: Trials (Sep 1, 2016).

TX

□ Full Text Translate

Study Design:

double-blind, multicentre, parallel, prospective, randomised

Study Endpoints:

Incidence of hospitalization due to RT-PCR confirmed RSV

safety issue: No

description: The incidence of RSV hospitalization 150 days post dose will be summarized by treatment group.

time frame: 150 days post dose

Safety and tolerability as assessed by the occurrence of all treatment emergent adverse events (TEAEs) and treatment emergent serious adverse events (TESAE)

safety issue: Yes

description: Safety of MEDI88987 will primarily be assessed and measured by the occurrence of all treatment-

emergent AEs and SAEs.

Other safety assessments will include the occurence of AESIs and NOCDs.

time frame: 360 days post dose

Single-dose serum concentrations of MEDI8897

safety issue: No

description: MEDI8897 serum concentration data will be tabulated by treatment group along with descriptive statistics. Terminal-phase half-life (t1/2) will be estimated using non-compartmental analysis, if data permit.

time frame: 360 days post dose

Incidence of anti-drug antibody (ADA) to MEDI8897 in serum

safety issue: No

description: The incidence of ADA to MEDI8897 will be assessed and summarized by number and percentage of

subjects that are ADA positive by treatment group.

time frame: 360 days post dose

Incidence of medically attended LRTI due to RT-PCR confirmed RSV

safety issue: No

description: The incidence of RSV LRTI (inpatient and outpatient) 150 days post dose will be based on RSV test results (performed centrally via RT-PCR) and objective clinical LRTI criteria and will be summarized by treatment group.

time frame: 150 days post dose

Study Details:

Status: initiated

Planned Start: September 2016 Planned Finish: April 2018

Design: double-blind, multicentre, parallel, prospective, randomised

Phase: II Endpoints:

Incidence of hospitalization due to RT-PCR confirmed RSV

safety issue: No

description: The incidence of RSV hospitalization 150 days post dose will be summarized by treatment group.

time frame: 150 days post dose

Safety and tolerability as assessed by the occurrence of all treatment emergent adverse events (TEAEs) and treatment emergent serious adverse events (TESAE)

safety issue: Yes

description: Safety of MEDI88987 will primarily be assessed and measured by the occurrence of all treatment-

emergent AEs and SAEs.

Other safety assessments will include the occurence of AESIs and NOCDs.

time frame: 360 days post dose

Single-dose serum concentrations of MEDI8897

safety issue: No

description: MEDI8897 serum concentration data will be tabulated by treatment group along with descriptive statistics. Terminal-phase half-life (t1/2) will be estimated using non-compartmental analysis, if data permit.

time frame: 360 days post dose

Incidence of anti-drug antibody (ADA) to MEDI8897 in serum

safety issue: No

description: The incidence of ADA to MEDI8897 will be assessed and summarized by number and percentage of

subjects that are ADA positive by treatment group.

time frame: 360 days post dose,

Incidence of medically attended LRTI due to RT-PCR confirmed RSV

safety issue: No

description: The incidence of RSV LRTI (inpatient and outpatient) 150 days post dose will be based on RSV test results (performed centrally via RT-PCR) and objective clinical LRTI criteria and will be summarized by treatment group.

time frame: 150 days post dose Study Center: MedImmune LLC Companies: MedImmune

Subject Details:

Planned No: 1500

Location: Argentina, Australia, Belgium, Brazil, Bulgaria, Canada, Chile, Czech Republic, Finland, France, Germany, Hungary, Italy, Multinational, New Zealand, Poland, Russia, South Africa, Spain, Sweden, United Kingdom, USA

Disease: Respiratory-syncytial-virus-infections

Patient Inclusion: Key 1. Healthy infants born between 29 weeks 0 days and 34 weeks 6 days GA 2. Infants who are entering their first full RSV season at the time of screening Key

Patient Exclusion: 1. Meets AAP or other local criteria to receive commercial palivizumab 2. Any fever (≥ 100.4°F [≥ 38.0°C], regardless of route) or lower respiratory illness within 7 days prior to randomization 3. Acute illness (defined as the presence of moderate or severe signs and symptoms) at the time of randomization 4. Active RSV infection (a child with signs/symptoms of respiratory infection must have negative RSV testing) or known prior history of RSV infection 5. Receipt of palivizumab or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccinationPlanned Patient Number: 1500

Patient Age Keywords: infant, neonate

RFF References

1.) ClinicalTrials.gov: US National Institutes of Health

WC Word count: 675

☐ Indexing (details) ☐ Cite

SU Subject Antivirals;

MEDI-8897;

Respiratory-syncytial-virus-infections, prevention

Related record ADRD accession number: .

Title A Phase 2b Randomized, Double-Blind, Placebo-controlled Study to Evaluate the

Safety and Efficacy of MEDI8897, a Monoclonal Antibody With an Extended Half-life

Against Respiratory Syncytial Virus, in Healthy Preterm Infants

Language English

DTYPE Document type Ongoing Trial

LA

PUB Publication title AdisInsight: Trials

PSTYPE Publication type Scholarly journals

STI Clinical trial ID 700275673 (Clinical Trials Insight), D5290C00003(), NCT02878330

(ClinicalTrials.gov: US National Institutes of Health)

PD,YR Publication date Sep 1, 2016

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 2016-09-01

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SAMPLE DOCUMENT: BEST EVIDENCE



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TI

AU, PUB

Secukinumab Inhibition of Interleukin-17A in Patients with Psoriatic Arthritis Mease, P J ; McInnes IB ; Kirkham, B; Kavanaugh, A; Rahman, P; et al. **New England Journal of Medicine** 373.14 (Oct 1, 2015): 1329-39.

TX Full Text Translate

Study Purpose:

This trial investigated the efficacy, safety and tolerability of secukinumab (AIN 457) in patients with active psoriatic arthritis.

Study Design:

double-blind, multicentre, parallel, prospective, randomised

Study Endpoints:

Proportion of patients achieving ACR20 response criteria on secukinumab 75 or 150 mg vs. placebo Assessed at week 24.

Percent of Subjects Achieving a PASI75 Response in the Subgroup of Subjects Who Have ≥3% Skin Involvement With Psoriasis at Baselinesafety issue: No description: A 75% reduction in the Psoriasis Area and Severity Index (PASI) score (PASI 75) is the current benchmark of primary endpoints for most clinical trials with end points of psoriasis time

. . .

☐ Indexing (details) ☐ Cite

SU Subject Rheumatic Disease;

Inflammation;

Immunological Disorders; Musculoskeletal Disorders;

Skin Disorders; Secukinumab;

Psoriatic-arthritis, treatment

SUBST Substance Generic name: Secukinumab
Route of Intravenous

administration:

Generic name: Secukinumab
Route of Intravenous

administration:

Generic name: Secukinumab
Route of Subcutaneous

administration:

Page 5

Title ΤI Secukinumab Inhibition of Interleukin-17A in Patients with Psoriatic Arthritis OTI Alternate title A Randomized, Double-blind, Placebo-controlled, Multicenter Study of Secukinumab to Demonstrate the Efficacy at 24 Weeks and to Assess the Long Term Safety, Tolerability and Efficacy up to 2 Years in Patients With Active Psoriatic Arthritis Study names: (FUTURE-1) Author Mease, P J; McInnes IB; Kirkham, B; Kavanaugh, A; Rahman, P; van der Heijde D; ΑU Landewe, R; Nash, P; Pricop, L; Yuan, J; Richards, H B; Mpofu, S Language English LA DTYPE Document type Best Evidence PUB **Publication title** New England Journal of Medicine SRC Source details New England Journal of Medicine, N-Engl-J-Med, 0028-4793, 373: 1329-39, No. 14, Oct 2015 Volume 373 VO ISS Issue 14 1329-39 PG **Pagination** ISSN **ISSN** 0028-4793 Publication type Scholarly journals **PSTYPE** STI Clinical trial ID 11416 (United Kingdom Clinical Research Network), 700202555 (Clinical Trials Insight), CAIN457F2306 (Novartis), CCRN622 (Comprehensive Clinical Research Network), EudraCT2011-000276-34 (European Clinical Trials Database), NCT01392326 (ClinicalTrials.gov: US National Institutes of Health) PD,YR **Publication date** Oct 1, 2015 Accession number AN 803145536 **Document URL** http://dialog.proquest.com/professional/docview /1719829126?accountid=174335 First available FAV 2015-10-08 **Updates** 2015-10-08 UD 2015-11-12 2015-11-19 2015-11-26 2016-01-22 2016-02-11 2016-03-31 2016-04-07 2016-05-26 2016-07-28 2016-08-18