

Assessment of Economic and Humanistic Burden of Refractory Chronic Spontaneous/Idiopathic Urticaria: Study Design of the First Observational Study, ASSURE-CSU

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Background

- Chronic spontaneous (also known as idiopathic) urticaria CSU/CIU is defined as the occurrence of wheals/hives, angioedema or both for 6 weeks or longer due to known or unknown causes and no identifiable external triggers^{1,2}
- Several studies show that the disease has an impact on different domains of health-related quality of life (HRQoL) such as³⁻⁵
 - Activities of daily living and social restrictions
 - Sleep disturbance and loss of energy
 - Emotional and psychological distress
- CSU/CIU has also an impact on society in terms of direct healthcare costs (i.e., costs incurred by patients) and indirect healthcare costs (i.e., loss of wages) and reduced performance at work or absence from work⁶
- Little published evidence is available on the actual burden of CSU/CIU on the patients who have inadequate response to H1-antihistamines (approximately 50% of the cases) and on healthcare resources and society

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Objective

- To identify and quantify the humanistic and economic burden of refractory CSU in patients, healthcare payers and society
- To evaluate the HRQoL, healthcare resource utilization, absence from work and productivity loss among patients with CSU who are symptomatic despite treatment and attend specialized centers or hospitals in each of the participating countries

Methods: Study Design



ASSURE-CSU: Non-interventional, International, Multicenter Study

Identify and quantify the economic and humanistic burden of illness in patients with CSU whose disease persists for >12 months and are symptomatic despite treatment

Retrospective medical chart review

- Patient demographics
- Baseline medical history
- Treatment patterns

- Total healthcare resource utilization and associated costs

UK
Germany
Italy
Canada
France
Spain
Netherlands

100 patients/country
TOTAL
~700 patients

Cross-sectional assessment of PROs and patient survey

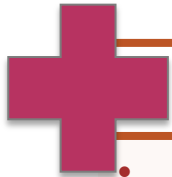
- Medical resources
- Out-of-pocket costs

7-day Patient Diary

- UAS7
- WPAI

- AE-QoL, CU-Q2oL
- DLQI, EQ-5D
- Angioedema characterization

Patient Selection Criteria





INCLUSION CRITERIA

- Clinician-confirmed diagnosis of CSU
- Received at least one treatment course with an H1-antihistamine
- Aged 18 years or older at the time of study enrolment
- Has been symptomatic for more than 12 months at least 3 days per week and is currently symptomatic, despite treatment
- Under the care of the participating physician or site for at least 12 months
- Provided informed consent
- Willing and able to complete the patient surveys

EXCLUSION CRITERIA

- Symptoms resolved within 12 months of diagnosis
- In remission/resolved, defined as more than 6 months untreated and without symptoms
- Urticaria is predominantly of an inducible form
- Participated in a CSU interventional study or clinical trial during the data collection period
- Unable to provide informed consent
- Not able and not willing to complete the patient surveys

Primary Study Outcomes

 MEDICAL RECORD DATA	 PATIENT REPORTED DATA
Demographic characteristics	AE-QoL, CU-Q2oL, DLQI, EQ-5D-3L
Baseline medical history	Healthcare resource utilization (other than in the charts, use of alternative medicine and out-of-pocket expenses)
Treatments received for CSU and response level	Disease Activity (determined with UAS7)
Duration and dosage of treatments	Angioedema history and characterization
Total healthcare resource utilization	Work days missed and productivity loss (WPAI)

AE-QoL: Angioedema QoL Questionnaire; CSU: Chronic Spontaneous Urticaria; CU-Q2oL: Chronic Urticaria QoL Questionnaire; DLQI: Dermatology Life Quality Index; EQ-5D-3L: EuroQoL-5D 3-level version; UAS7:Urticaria Activity Score 7; WPAI: Work Productivity and Activity Impairment

Data Analyses

- All study measures will be summarized descriptively through the tabular display of mean values, medians, ranges, and standard deviations for continuous variables and frequency distributions for categorical variables
- Outcomes will be compared across disease severity levels
- Costs will be calculated for the resource use items collected using medical records and patient surveys by the application of unit costs to each resource use estimate
- A set of multivariable analyses may be conducted to assess the adjusted differences in resource utilization and cost outcomes of interest between disease severity levels
- All analyses will be performed using SAS for Windows statistical software, version 9.3 or higher (SAS Institute, Inc., Cary, North Carolina, US)

Conclusions

- ASSURE-CSU is the first international study assessing the burden of refractory CSU on patients, healthcare payers and society
- The study will contribute to the better understanding of this condition in terms of symptoms and HRQoL as well as its impact on patient's daily life, work and productivity
- The study will allow a thorough description of resources from healthcare payer, patient and society perspective and yield a holistic approach of disease management in the future

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Conflict of Interest

- Dr. Maria-Magdalena Balp is a permanent employee of Novartis Pharma AG, Basel, Switzerland

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