STUDIENTITEL	**Evaluation of psychological stress as an influencing factor on the effectiveness and quality of life during therapy with immune checkpoint inhibitors**
STUDY TYPE	Prospective, registry
PROJECT LEAD / COORDINATION (YMO)	Dr. Med. Tabea Fröhlich Medizinische Hochschule Hannover Klinik für Hämatologie, Hämostaseologie, Onkologie und Stammzelltransplantation, OE 6860 Carl-Neuberg-Str. 1 30625 Hannover 0511 532 3020 Froehlich.tabea@mh-hannover.de
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CONDITION	Any solid tumor
DESIGN	Multicenter, observational, prospektive cohort study
OBJECTIVE(S)	- Influence of psychological stress on the response to immune checkpoint inhibitor (ICI) therapy - Influence of psychological stress on the occurrence of immune-mediated side effects during therapy with ICI - Relationship between the presence of psychological stress, gut microbiome, tumor microenvironment, immune cell distribution in the blood and laboratory chemical stress parameters - Detection of predictive markers and starting points for interventions
INTERVENTION(S)	n/a
BACKROUND/RATIONALE	Psychological stress appears to have an influence on tumor development. The relationship between the occurrence of psychological stress and the course of treatment with immune checkpoint inhibitor therapies (ICI) has not yet been well investigated. The observational study with translational approaches to investigate the interactions with laboratory chemical parameters, tumor microenvironment, immune cell distribution in the blood and intestinal microbiome is intended to develop a better understanding of ICI therapies, evaluate predictive markers and find starting points for interventions to improve the effectiveness and quality of life under therapy with ICI.
KEY EXCLUSION CRITERIA	Lack of ability to provide information, Lack of a written declaration of consent

KEY INCLUSION CRITERIA	Male and female patients over 18 years of age with tumor diseases who are capable of being informed and are being treated with ICI therapy
MAIN METHODS	Psychological stress (GAD-7 / PHQ-9) Gut microbiome Flow cytometry immune cell distribution in the blood Tumor microbiome
SAMPLE SIZE	Study cohort: All patients over 18 years of age with tumor diseases who are capable of being informed and are being treated with ICI therapy
TRIAL DURATION	2025-2028
PARTICIPATING CENTERS	Hannover (MHH)
FURTHER CENTERS DESIRED?	yes
NUMBER of PATIENTS	200
CURRENT NUMBER of PATIENTS	0