Prognostic Study Planning Guide

As you plan your study, record your intentions for each of the suggested items prior to data collection to ensure that you have the detail required for your future manuscript. Each unchecked box may result in higher risk of bias of study results, lowering the quality of your final publication. Additional details for each domain are provided below the checklists.

Suggested Study Design: Prospective Cohort

Title

Author(s)/Affiliation

Date

Patient Description Additional Details

- ☐ Sample representative of the target population
- ☐ Exposed/unexposed patient groups described, distinguishable, and free of outcome at baseline

Patient Recruitment Additional Details

- ☐ Recruitment setting/location
- ☐ Recruitment criteria
- ☐ Recruitment methods
- ☐ Number of participants in each comparison group
- ☐ Disease status of participants in each comparison group
- ☐ Baseline patient characteristics/demographics for all comparison groups

Patient Enrollment Additional Details

- ☐ Informed consent and study approval status
- ☐ Consecutive enrollment
- ☐ Inclusion criteria
- ☐ Exclusion criteria

Materials Additional Details

- ☐ Measurement tools/instruments
- ☐ Referenced validity of measurement tools

General Methods Additional Details

- ☐ Duration of the study
- ☐ Credibility of examiner background and training
- ☐ Pre-determined prognostic factors and outcomes of interest
- ☐ Equal measurement methods for prognostic factors of interest
- ☐ Equal measurement methods for outcomes of interest (Method of diagnosis)

Details and Procedures Additional Details

- ☐ Process details for tests and/or measurements
- ☐ Threshold/cutoff values used for dependent and independent variables
- ☐ Duration between examinations
- ☐ Equal follow-up times
- ☐ Intended data/group comparisons
- ☐ Rescue medication allowed (if applicable)

Statistical Modeling and Analysis Additional Details

- ☐ Software used for statistical analysis
- ☐ Statistical tests and/or regression models used
- ☐ Calculations, effect measures, and variables used for group data comparisons
- ☐ Statistical adjustment/control method used for possible confounders
- ☐ Clear description of what confounding variables were considered
- ☐ Model building/variable selection strategy described and appropriate
- ☐ Description of missing data with management/control strategy
- ☐ Description of how statistical assumptions were tested

General Results Additional Details

- ☐ Final examined patient count
- ☐ Study Duration
- ☐ Scale direction of all factors and outcome measurement tools
- ☐ Rate and Details of patients lost to follow-up
- ☐ Pre-specified prognostic factors and outcomes
- ☐ Rationale for missing data
- ☐ Analysis accounting for missing data (e.g. LOCF, imputation, etc.)
- ☐ Rescue medication consumed (if applicable as a possible confounder)

Data Comparisons Additional Details

- ☐ Equal follow-up times for all groups
- ☐ Data evaluated at each follow-up for all groups
- ☐ Odds ratios, risk ratios, risk differences, log odds, hazard ratios, or any other validated/appropriate summary statistic with respective confidence limits
- ☐ Descriptions and measurements for potential confounders
- ☐ Explanation of data tables

ADDITIONAL DETAILS

Patient Description

Standard (Low risk of bias)

- Study participants are representative of the larger population of interest
- Exposed and unexposed patient groups are described, distinguishable, and have not yet been diagnosed or confirmed to have the target outcome/illness

Discouraged (High risk of bias)

- Healthy and pre-diagnosed patients included in the analysis (non-nested case control design)

Patient Recruitment

Standard (Low risk of bias)

- Patients should be recruited and examined prospectively at one location or similar locations (e.g. multi-center study in three county hospitals in Southern Illinois)
- Patients should be recruited following a pre-defined criteria for how, when, why, and by whom they will be recruited
- Matching techniques should be done upon inclusion if you do not plan to statistically control for potential confounders
- A complete count of patients that were included should be reported as well as the patient count for any groups or categories of patients
- The patient characteristics and disease status (e.g. undiagnosed, symptomatic, etc.) should be reported and described for all patients/groups

Discouraged (High risk of bias)

- Patients or groups with unspecified or unclear patient counts, recruitment strategies, or uncontrolled potential confounders

Patient Enrollment

Standard (Low risk of bias)

- The study should be approved with informed consent to meet safety, ethics, and regulation standards
- A description should be provided of how, and within what population, enrollment will be conducted
- Patients should be consecutively enrolled by including all patients that fit the criteria and agree to participate (e.g. avoiding "cherry picking")
- A detailed list of criteria should be set for patients to be included or excluded from the study

Discouraged (High risk of bias)

- Unapproved or unorganized studies with uninformed patients
- Enrollment of patients by convenience sampling or non-consecutive enrollment
- Including or excluding patients with limited details or rationale
- Including patients with possible confounders (e.g. comorbidities, variant patient characteristics) with no statistical method for control or matching technique

Materials

Standard (Low risk of bias)

- Describe the details (range, direction, source, etc.) and reference the validity and/or reliability of any scales, questionnaires, categorization techniques, medical devices, etc. that will be used at any stage of the study duration

Discouraged (High risk of bias)

- Use of invalidated or unapproved scales, questionnaires, devices, etc. to categorize and measure patient outcomes or prognostic factors

General Methods

Standard (Low risk of bias)

- Determine and report the duration of the recruitment and study periods
- Ensure examiner credentials are provided with proper certification to analyze and/or interpret patient factors and outcomes
- Describe pre-defined primary and secondary prognostic factors and outcomes of interest
- Measure all patients/groups in the same way and with the same tools; this also applies to the method of diagnosis for recruitment

Discouraged (High risk of bias)

- Examiners that are not trained, credentialed, and/or approved to use or interpret any aspect of their function in the study
- Investigating outcomes or prognostic factors that are not predefined and described
- Patients/groups measured at different time-points or through use of different outcome or prognostic measures

Details and Procedures

Standard (Low risk of bias)

- Describe how each prognostic factor of interest will be measured including a process description that permits replication and predetermined threshold/cutoff values for predictor and outcome variables
- Choose valid and referenced threshold/cutoff values for diagnosis confirmation, inclusion, and/or outcome response
- Choose time-points for follow-up that are clinically relevant and allow for proper analysis of the population at risk
- Ensure each patient will be measured in the same way and at the same time-points across all groups being directly compared
- Describe all groups and measures that will be compared and how they will be compared in the analysis of the results
- Describe dosage and administration of rescue medication if applicable as a potential confounder

Discouraged (High risk of bias)

- Lack of description of any of the measurement procedures or comparisons of interest
- Use of inapplicable or invalidated devices or outcome measures used for the condition of interest
- Threshold/cutoff values for diagnosis or outcome measurement that are unlisted or clinically irrelevant
- Unlimited allowance of rescue medication or rescue medication that may have confounding effects on the intervention or outcome of interest
- Patients measured differently within individual groups or across comparator groups

Statistical Modeling and Analysis

Standard (Low risk of bias)

- Describe how, and by whom, the data was documented and organized to prepare for analysis
- Describe any equations that will be used in preparation and analysis including: power analysis, odds ratios, risk ratios, confidence limits, significance, etc.
- Create data tables (e.g. odd/risk ratios with confidence limits at each follow-up time) and statistical models (e.g. regression analysis) that will assist with comparisons, control for possible confounding or baseline differences, and interpretation of the results for desired conclusions
- Be sure to use at least 10 participants per group for every factor included in the final regression analysis
- Clearly describe statistical methods, potential confounders included in the model, and statistical control methods (e.g. multiple OLS regression, matching with paired t-test, etc.)
- Clearly describe methods used for predictor selection for inclusion in the model (e.g. forward stepwise selection, past literature, etc.) - If stepwise method used, model stability validation done through bootstrap re-sampling or other comparable method.
- Clearly describe methods to deal with missing data (Imputation, LOCF, ITT, etc.) as well as statistical assumptions testing.

Discouraged (High risk of bias)

- Insufficient data or calculations that will not allow the reader to clearly observe significance or raw data to evaluate odds or risk ratios (e.g. patient counts, confidence limits, etc.)
- Unclear, invalid, or absent description of statistical tests, model building, variable selection strategy, or statistical assumptions testing method.
- Incomplete description of all the variables included in final statistical model
- Missing predictor/outcome data and management/control strategy

General Results

Standard (Low risk of bias)

- All patient/group data needed to analyze all target comparisons is organized in a way that allows complete analysis of all necessary calculations
- The number of patients with missing predictor and/or outcome data from recruitment to final analysis is presented
- Target prognostic factor and outcome results are consistent with pre-determined target factors and outcome measures listed in the study protocol/methods
- All outcome and prognostic factor measurements are made on validated tools or scales with range and direction indicated (e.g. VAS pain scale: 0-100 where 100 is best)
- Any missing data or observations are described in detail with rationale provided for those patients/groups
- Statistical results/models account for missing predictor/outcome data through imputation (e.g. multiple imputation, LOCF, etc.) or models that allow for missing values (e.g. mixed models).
- Differences and significance of rescue medication consumption between intervention groups if applicable

Discouraged (High risk of bias)

- Data presented at recruitment, during follow-up, or in the final analysis that lacks agreement and/or lacks appropriate rationale for missing data, observations, or patients/groups
- Missing data or observations without adjustment and appropriate rationale
- Outcomes presented in analysis that are not predefined and listed in the study protocol/ methods
- Lack of statistical model and/or rationale to account for missing predictor/outcome data when accompanied by a large loss to follow-up

Data Comparisons

Standard (Low risk of bias)

- All patient/group data are evaluated at the same time-point and are organized in a way that allows for all target comparisons and calculations (e.g. dichotomous events/non-events, odds/risk ratios, etc.) including confidence limits and determination of significance for each calculation
- Rationale provided for the structure of the data tables, statistical model, target comparisons, and data presented is
- Description of potential confounders and statistical control for these confounders is provided

Discouraged (High risk of bias)

- Data presented supports conclusions but is insufficient for necessary calculations, and the structured data tables and statistical modeling do not allow for target comparisons and conclusions to be made
- Group data not presented individually and/or target time-points that do not include consistent reporting with all other time-points