CHAPTER IV

RESEARCH METHOD

4.1 Research fields

This study belongs to the field of Internal Medicine, specifically the field of Infectious and Tropical Disease.

4.2 Research location and period

This study was conducted on March-May 2014. A preliminary survey was conducted on November 2013 – February 2014. The study took place in the Voluntary Counseling and Testing (VCT) Clinic of Dr. Kariadi Hospital Semarang. The laboratory tests were analyzed in the Central Laboratory of Dr. Kariadi Hospital Semarang.

4.3. Research design

This study was an observational analytic study using cross-sectional method.
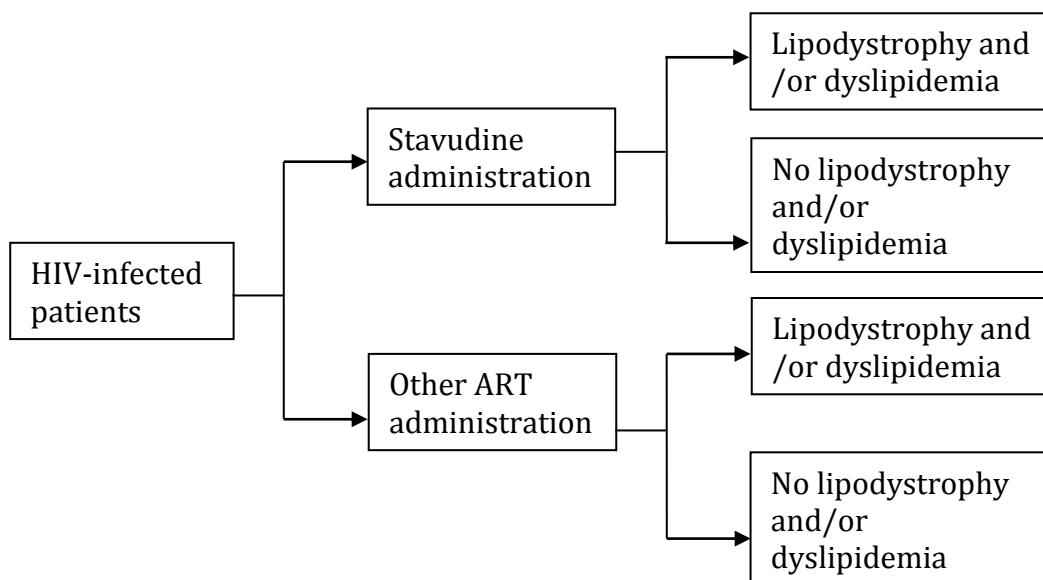
Figure 3. Research Design

4.4. Population and Samples

4.4.1. Targeted Population

Targeted population of this study was all HIV-infected patients with stavudine administration.

4.4.2. Reached Population

Reached population of this study was all HIV-infected patients with stavudine administration in Dr. Kariadi Hospital Semarang.

4.4.3 Samples

Samples of this study were reached populations meeting the inclusion criteria.

4.4.3.1 Inclusion Criteria

Samples were taken with inclusion criteria:

- HIV-infected patients administered with stavudine containing regimens in Dr. Kariadi Hospital for stavudine group.

- HIV-infected patients administered with zidovudine, lamivudine, and nevirapine for control group.

4.4.3.2 Exclusion Criteria

Samples were excluded if they meet one of these criteria:

- In pregnancy state.

- Age < 15 years.

- Having a history of lipodystrophy and/or dyslipidemia prior the initiation of ART.

4.4.4 Sampling Method

Samples were drawn using consecutive sampling method according to patients' arrival in Dr. Kariadi Hospital. Patients meeting the inclusion criteria were included in this study. The sample taking were finished once the required sample size was met.

4.4.5. Sample Size

The sample size was estimated using formula for estimated single proportion.

$$N = \frac{Z^2_{1-\frac{\alpha}{2}} \, P(1-p)}{d^2}$$

N = estimated single proportion

p = estimated prevalence

d = margin of error

α = probability of type I error

The estimated prevalence of dyslipidemia in HAART receiving patients was 4.5%. The confidence interval (CI) for this study was 95% while the margin of error was 10%. The minimum number of required sample for this study was 17 patients.

4.5 Research Variables

4.5.1 Dependent Variables

- Lipodystrophy
- Dyslipidemia

4.5.2 Independent Variable

- Stavudine administrations in HIV-infected patients
- Age
- Sex

- CD4 count

- Duration of therapy

4.5.3 Confounding Variables

- Direct consequence of HIV infection

- Protease inhibitors administration

- History of metabolic syndrome

- Sedentary lifestyle

- Obesity

- Cigarette smoking

4.6 Operational Definitions

Table 6. Operational definitions

No	Variable	Unit	Scale
1	Lipodystrophy Lipodystrophy was diagnosed from clinical examination using LSGS score. Lipodystrophy was diagnosed if the overall score > 7 or there were severe fat changes in ≥ 1 body location. 1. Absent 2. Lipodystrophy		Nominal
2	Triglycerides (TG) The level of TG in patient's serum taken after a 9 hours fasting. Dyslipidemia was defined if TG ≥ 150 mg/dL. 1. Normal 2. Dyslipidemia	mg/dL	Nominal
3	Total cholesterol (TC) The level of TC in patient's serum taken after a 9 hours fasting. Dyslipidemia was defined if TC ≥ 200 mg/dL. 1. Normal 2. Dyslipidemia	mg/dL	Nominal
4	Low density lipoprotein cholesterol (LDL-c) The level of LDL-c in patient's serum taken after a 9 hours fasting. Dyslipidemia was defined if LDL-c ≥ 130 mg/dL. 1. Normal 2. Dyslipidemia	mg/dL	Nominal
5	High density lipoprotein cholesterol (HDL-c) The level of HDL-c in patient's serum taken after a 9 hours fasting. Dyslipidemia was defined if HDL-c ≤ 40 mg/dL. 1.Normal 2. Dyslipidemia	mg/dL	Nominal
6	Age Age of the patient when data was collected. 1. < 35 years 2. ≥ 35 years	years	Ordinal
7	Sex Sex of the patient when data was collected. 1. Male 2. Female		Nominal
8	CD4 Count CD4 T cell count of the patient when data was collected. 1. < 200 cells/mm^3 2. ≥ 200 cells/mm^3	cell/mm^3	Ordinal
9	Duration of therapy Duration of stavudine therapy when data was collected. 1. < 18 months 2. ≥ 18 months	months	Ordinal

4.7. Data Collection

4.7.1 Materials and Equipments

The materials used for data collection were case record form to determine routine demographic information and LSGS score sheet to determine lipodystrophy status. Serum lipid profile results were used to determine dyslipidemia. The equipments used in this study were syringe needle and tourniquet.

4.7.2 Type of Data

The data collected for this study were primary data taken from case record form, LSGS sheets, and laboratory results.

4.7.3 Procedure

The diagnosis of lipodystrophy was taken from LSGS score sheet by attending physician in VCT clinic. Routine demographic informations such as age, sex, CD4 count, and duration of therapy were taken from case record forms. Patients were asked to fast overnight for 9 hours for lipid profile test. Lipid profiles checked were TG, TC, HDL-c, and LDL-c blood level. A 5 ml blood sample was drawn from the patient's median cubital vein. The blood samples were analyzed using automated analyzer in Central Laboratory Dr. Kariadi Hospital.

4.8 Research Protocols
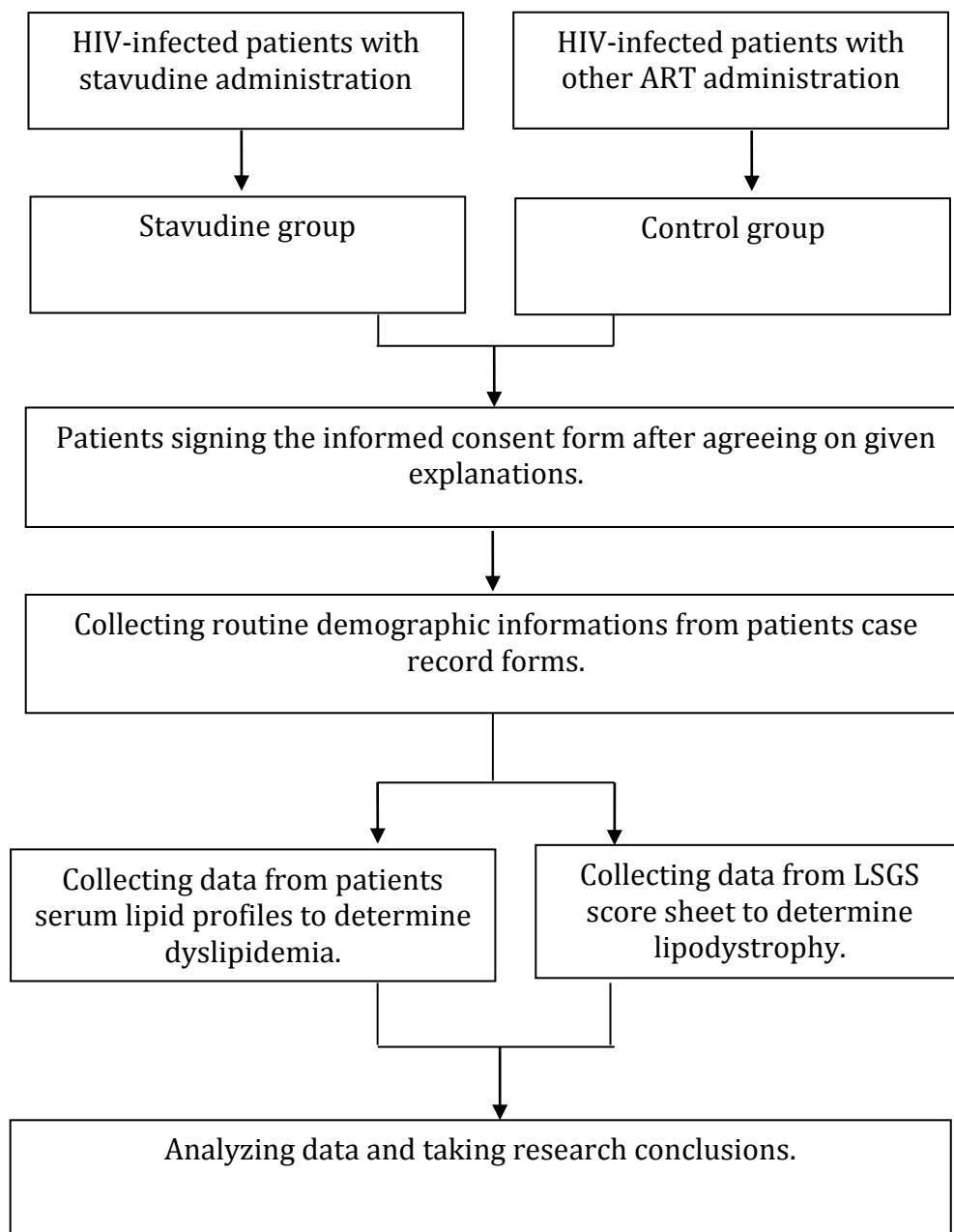
Figure 4. Research Protocol Framework

4.9 Data Analysis

Collected data were edited, cleaned, and tabulated before analyzed with statistical tests. Chi-square test was used to determine the association between age, sex, current CD4 count, and duration of therapy with the incidence of lipodystrophy and dyslipidemia. Ineligible data for chi-square test was analyzed using Fischer's Exact Test. Stavudine administration and routine demographic informations was considered to have correlation with the incidence of dyslipidemia and lipodystrophy if $p < 0.05$.

4.10 Research Ethics

All of data collections and research was under permission of the Commission of Health Research Bioethics Faculty of Medicine Diponegoro University/Dr. Kariadi Hospital Semarang Indonesia.

4.11 Research Schedule

Table 7. Research Schedule

Activities	February 2014		March 2014				April 2014			July 2014
Weeks	W3	W4	W1	W2	W3	W4	W1	W2	W3	W4
Research Proposal	■	■								
Research Preparation			■							
Data Collection				■	■	■				
Data Analysis							■			
Research Report								■	■	■
Report Presentation										■