LAMPIRAN

Lampiran 1

Surat Persetujuan Proposal Penelitian

UNIVERSITAS PEMBANGUNAN NASIONAL VETERAN JAKARTA
FAKULTAS KEDOKTERAN
JL. RS. Fatmawati Pondok Labu – Jakarta Selatan 12450 Telp. 75905242 – 7669803 Fax. 7669803

PERSETUJUAN PROPOSAL PENELITIAN

Kami yang bertandatangan di bawah ini adalah pembimbing skripsi dari mahasiswa

Nama : Hanny Mutiarayni Balga

NRP : 1710211065

Judul Skripsi : PENINGKATAN KADAR ENZIM TRANSAMINASE SEBAGAI PREDIKTOR DIABETES MELITUS TIPE 2 PADA PASIEN PERLEMAKAN HATI NON ALKOHOLIK : *LITERATURE REVIEW*

Telah menyetujui pra proposal skripsi (BAB I sampai dengan BAB III) dari mahasiswa tersebut diatas dan **telah menyetujui untuk dilaksanakan penelitian tersebut di atas.**

Demikian surat persetujuan ini dibuat untuk dipergunakan sebagaimana mestinya.

Jakarta, 4 Juli 2020

Penguji Utama	Pembimbing
dr. Ryan Herardi, Sp.PD	dr. Tuty Rizkianti, Sp.PK

Lampiran 2

Tabel Ekstraksi Data

TABEL EKSTRAKSI DATA

No	Nama Peneliti dan Tahun Penelitian	Judul Penelitian	Metode atau Desain Penelitian	Populasi (sampel penelitian)	Definisi Variabel	*Follow up* (tahun)	Pemeriksaan enzim hepar	Analisis Data	Hasil Klinis (interval kepercayaan (CI) 95%)
1.	Chen *et al.* (2017)	"*Liver Fat, Hepatic Enzymes, Alkaline Phospatase, and the Risk of Incident Type 2 Diabetes : a Prospective Study of 132.377 Adults*"	Kohort Prospektif	Sampel : 132.337 individu non diabetik (64.875 pria dan 67.502 wanita) Kriteria inklusi : 1. Partisipan yang melakukan pemeriksaan kesehatan 2	Diabetes adalah seseorang yang memiliki kadar glukosa darah puasa (GDP) ≥ 126 mg/dL	5.8	ALT, AST, GGT, dan ALP	Menggunakan model regresi Cox proportional hazard	- Diantara 132.377 individu non diabetik, 6555 terdiagnosis diabetes dengan rata-rata *follow up* 5.8 tahun - Menggunakan model regresi cox multiple didaptkan NAFLD, ALT, AST, GGT, dan ALP secara signifikan

				atau lebih antara 1 Januari 1996 dan 31 Desember 2014 2. Usia 35-79 tahun Kriteria ekslusi 1. Terdiagnosis DM tipe 2 2. Perlemakan hati yang disebabkan karena virus hepatitis B (positif antigen permukaan HBV)	atau dilaporkan melakukan pengobatan obat anti hipergli kemi Faktor resiko diabetes : NAFLD ditegakkan dengan radiolog				merupakan faktor resiko independen insidensi kejadian diabetes baik pria maupun wanita dengan menyesuaikan nilai *hazard ratio* (HR) dan interval kepercayaan (CI) 95% adalah NAFLD 2.08 (1.93-2.23), ALT 1.27 (1.16-1.38), AST 1.23 (1.131.34), GGT 1.58 (1.46-1.72), ALP 1.37 (1.17-1.60) pada pria dan 2.65 (2.43-2.88), 1.56 (1.37-1.77), 1.18 (1.04-1.34), 1.48 (1.32-1.65) dan 1.44 (1.25-1.66) pada

				3. Konsumsi alkohol berlebih → GGT secara pria = >100 U/L atau wanita = 78 U/L, rasio AST:ALT = >2 atau mengkonsumsi ethanol untuk pria > 140 gr/minggu atau 50 gr /kali minum dan wanita >70 gr/minggu	is secara ultrasonografi (ya/tidak) Kategori level enzim hepar dibagi menjadi tinggi (ALT > 33 U/L; AST > 27 U/L; GGT ≥50 U/L(pria),≥ 39				wanita.

				atau 40 gr/kali minum 4. Hilang informasi 1 atau lebih faktor resiko 5. Individu yang mengikuti penelitian kurang dari 365 hari 6. Konsumsi obat anti hiperglikemia selama penelitian tapi tidak melakukan	U/L (wanita) ; ALP > 220 U/L (1996-2004) atau > 104 U/L (2005-sekarang) dan normal (kebalikannya)				

				pelaporan kepada peneliti					
2.	Zhang *et al.* (2018)	"*Liver Enzymes, Fatty Liver and Type 2 Diabetes Mellitus in Jinchang Cohort : a Prospective Study in Adults*"	Kohort Prospektif	Populasi yang berasal dari Jinchang Cohort Study di Kota Jinchang, provinsi Gansu, China. Sampel : 33.355 orang Kriteria inklusi 1. Melakukan pemeriksaan lengkap selama penelitian 2. Terdiagnosis DM tipe 2	Diabetes adalah kadar GDP ≥ 126mg/dL (7.0 mmo/L) atau memiliki riwayat didiagnosis diabetes atau sedang dalam	2.2	ALT, AST dan GGT	- Uji T Independen - Regresi cox hazard	- Mean usia subjek adalah 46 tahun dikedua jenis kelamin - Selama *follow up* rata-rata 2.2 tahun didapatkan 1051 insidensi kasus diabetes. Cumulative incidence pada *fatty liver* 8.05-9.02% dan 2.25-4.10% pada populasi normal - Sampel yang terkena diabetes dibagi menjadi 2 grup berdasarkan konsentrasi enzim

					pengobatan. *Fatty liver* didiagnosis menggunakan USG abdominal menggunakan kriteria standar Kadar ALT > 40 U/L,				(normal,abnormal) dan ada atau tidaknya *fatty liver* - Pada kelompok *fatty liver* insidensi DM tipe 2 lebih tinggi kelompok enzim hepar yang abnormal pada wanita, kecuali GGT (ALT : 13.82%> 8.25%, AST : 11.87% > 9.27%, GGT : 10.47> 9.90%) - HR insidensi DM tipe 2 dibandingkan dengan kelompok enzim normal pada *fatty liver* adalah ALT 1.23 (1.10-1.50), AST 1.30 (1.07-1.59) dan

					AST> 40 U/L dan GGT > 50 U/L				GGT 1.34 (1.08-1.65) - Analisis regresi cox multiple : abnormal ALT dan GGT HR 1.53 (1.18-1.98), sedangkan AST tidak berhubungan dengan kejadian diabetes.
3.	Shen *et al.*(2018)	"*Non Alcoholic Farry Liver Disease and Risk of Diabetes : A Prospective Study in China*"	Kohort Prospektif	Sampel : 41.650 orang usia 18-97 tahun dari komunitas Kailuan Kriteria inklusi : 1. Melakukan pemeriksaan kesehatan lengkap 2. Usia 18-97 tahun	Diabetes adalah kadar GDP ≥ 7.0 mmol/L atau sedang melakukan mengobatan	3.6	ALT	Model regresi Cox proportional hazard	- 2763 orang terdiagnosis diabetes dengan rata-rata *follow up* selama 3.6 tahun - Peningkatan ALT berhubungan dengan peningkatan resiko kejadian diabetes setelah dilakuka penyesuaian untuk NAFLD dan kovariat

				Kriteria ekslusi : 1. Terdiagnosis diabetes 2. Meminum alkohol 3. Antigen permukan hepatitis B positif 4. Sirosis hati 5. Riwayat penyakit ganas 6. Hilang atau tidak lengkapnya data seperti intake alkohol, informasi	dengan insulin atau obat oral hipoglikemi. Penilaian NAFLD menggunakan USG abdominal Steatosis liver didiagnosis				variabel perancu 12% (95% CI, 2-22%) - Hubungan peningkata ALT dengan kejadian diabetes lebih banyak terjadi pada partisipan dengan NAFLD (HR = 1.23 (1.09-1.37); P, 0.001) dibandingkan tanpa NAFLD (HR = 1.01 (0.87-1.19). Interaksi P antara peningkatan ALT dan NAFLD adalah 0.25 - Pada analisis sensitivitas, hubungan signifikan anatara NAFLD/ALT dan resiko diabetes tidak berubah setelah

				dasar seperti diabetes atau yang tidak berpatisipasi selama *follow up*	berdasarkan derajatnya yaitu *mild*, *moderate*, dan *severe*. NAFLD didiagnosis jika 1) ditemukan adanya kriteria diagnosis dari				melakukan ekslusi partisipan dengan serum kreatinin ≥ 176.8 µmol/L atau peningkatan ALT atau partisipan yang dilaporkan konsumsi alkohol ≤ 3 kali/bulan

					perlemakan hati; 2) tidak mengkonsumsi alkohol selama atau awal penelitian dan 3) antigen permukaan hepatitis B negatif dan tidak memilik				

					i sirosis hati. Peningkatan ALT menggunakan kriteria Prati yaitu > 19 u/L untuk wanita dan 30 U/L untuk pria				
4.	Choi *et al*. (2013)	" *Increased Risk of Type 2 Diabetes in*	Kohort Retrospektif	Sampel : 7849 orang tanpa	Diabetes adalah	4 (47.2 bulan)	ALT	- ANC OVA	- 7849 subjek dibagi menjadi 4 kelompok

		Subjects with Both Elevated Liver Enzymes and Ultrasonographycally Diagnoses Non Alcoholic Fatty Liver Disease : A 4- year Longitudinal Study"		diabetes yang melakukan pemeriksaan kesehatan rutin selama 5 tahun di Kangbuk Samsung Hospital Total Healthcare Center Kriteria inklusi : 1. Tidak terdiagnosis diabetes 2. Melakukan pemeriksaan kesehatan lengkap *3. Menyetujui inform*	kadar GDP ≥ 126mg/dL atau HbA1C 6.5% *Fatty liver* didiagnosis menggunakan USG abdominal yang sesuai dengan kriteria standar			- Uji ANOVA 2 arah - Regresi Cox proportional hazard	(kontrol, ALT meningkat, steatosis dan kombinasi) - Total dari 435 subjek (5.5%) mengidap diabetes dengan mean *follow up* hampir 4 tahun (47.2 bulan) dengan angka insidensi diabetes adalah kontrol (3.5%), ALT meningkat (4.6%), steatosis (7.3%) dan kombinasi (11.8%) - Pada model Cox proportional hazard , HR insidensi diabetes meningkat pada kelompok ALT,

				consent Kriteri Ekslusi 1. Terdiagnosis diabetes (GDP ≥ 126mg/dL atau HbA1c 6,5%) 2. Intake alkohol 20g/ hari 3. Positif antigen permukaan hepatitis B (HbsAg) atau hepatitis C antibody (HCV)	Kadar serum ALT < 30 IU/L pada pria dan 19 IU/L pada wanita adalah norma;				steatosis, dan kombinasi - Tidak didapatkan adanya interaksi antara status ALT dengan steatosis untuk resiko kejadian diabetes (p = 0.334) - Seteleah penyesuaian multivariat seperti usia, gender, BMI, TG, HDL-C, tekanan darah sistolik, kegagalan glukosa darah puasa (IFG), aktivitas fisik, status merokok, dan konsumsi alkohol, kelompok kombinasi memiliki peningkatan

				4. Kelainan ultrasonografi abdominal (sirosis hepar atau keganasan) 5. Data tidak lengkap atau hilang					HR 1.64 (1.27-2.13) untuk menjadi diabetes dibandingkan dengan kelompok kontrol

Lampiran 3

Checklist CASP Kohort 2018

CASP
Critical Appraisal Skills Programme

www.casp-uk.net
info@casp-uk.net
Summertown Pavilion, Middle Way Oxford OX2 7LG

CASP Checklist: 12 questions to help you make sense of a **Cohort Study**

How to use this appraisal tool: Three broad issues need to be considered when appraising a cohort study:

- Are the results of the study valid? (Section A)
- What are the results? (Section B)
- Will the results help locally? (Section C)

The 12 questions on the following pages are designed to help you think about these issues systematically. The first two questions are screening questions and can be answered quickly. If the answer to both is "yes", it is worth proceeding with the remaining questions. There is some degree of overlap between the questions, you are asked to record a "yes", "no" or "can't tell" to most of the questions. A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

About: These checklists were designed to be used as educational pedagogic tools, as part of a workshop setting, therefore we do not suggest a scoring system. The core CASP checklists (randomised controlled trial & systematic review) were based on JAMA 'Users' guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL, and Cook DJ), and piloted with health care practitioners.

For each new checklist, a group of experts were assembled to develop and pilot the checklist and the workshop format with which it would be used. Over the years overall adjustments have been made to the format, but a recent survey of checklist users reiterated that the basic format continues to be useful and appropriate.

Referencing: we recommend using the Harvard style citation, i.e.: *Critical Appraisal Skills Programme (2018). CASP (insert name of checklist i.e. Cohort Study) Checklist. [online] Available at: URL. Accessed: Date Accessed.*

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Paper for appraisal and reference:.....

Section A: Are the results of the study valid?

1. Did the study address a clearly focused issue?

Yes ☐
Can't Tell ☐
No ☐

HINT: A question can be 'focused' in terms of
- the population studied
- the risk factors studied
- is it clear whether the study tried to detect a beneficial or harmful effect
- the outcomes considered

Comments:

2. Was the cohort recruited in an acceptable way?

Yes ☐
Can't Tell ☐
No ☐

HINT: Look for selection bias which might compromise the generalisability of the findings:
- was the cohort representative of a defined population
- was there something special about the cohort
- was everybody included who should have been

Comments:

Is it worth continuing?

3. Was the exposure accurately measured to minimise bias?

Yes ☐
Can't Tell ☐
No ☐

HINT: Look for measurement or classification bias:
- did they use subjective or objective measurements
- do the measurements truly reflect what you want them to (have they been validated)
- were all the subjects classified into exposure groups using the same procedure

Comments:

4. Was the outcome accurately measured to minimise bias?

Yes ☐
Can't Tell ☐
No ☐

HINT: Look for measurement or classification bias:
- did they use subjective or objective measurements
- do the measurements truly reflect what you want them to (have they been validated)
- has a reliable system been established for detecting all the cases (for measuring disease occurrence)
- were the measurement methods similar in the different groups
- were the subjects and/or the outcome assessor blinded to exposure (does this matter)

Comments:

5. (a) Have the authors identified all important confounding factors?

Yes ☐
Can't Tell ☐
No ☐

HINT:
- list the ones you think might be important, and ones the author missed

Comments:

5. (b) Have they taken account of the confounding factors in the design and/or analysis?

Yes ☐
Can't Tell ☐
No ☐

HINT:
- look for restriction in design, and techniques e.g. modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors

Comments:

6. (a) Was the follow up of subjects complete enough?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider
- the good or bad effects should have had long enough to reveal themselves
- the persons that are lost to follow-up may have different outcomes than those available for assessment
- in an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort

6. (b) Was the follow up of subjects long enough?

Yes ☐
Can't Tell ☐
No ☐

Comments:

Section B: What are the results?

7. What are the results of this study?

HINT: Consider
- what are the bottom line results
- have they reported the rate or the proportion between the exposed/unexposed, the ratio/rate difference
- how strong is the association between exposure and outcome (RR)
- what is the absolute risk reduction (ARR)

Comments:

8. How precise are the results?

HINT:
- look for the range of the confidence intervals, if given

Comments:

9. Do you believe the results?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider
- big effect is hard to ignore
- can it be due to bias, chance or confounding
- are the design and methods of this study sufficiently flawed to make the results unreliable
- Bradford Hills criteria (e.g. time sequence, dose-response gradient, biological plausibility, consistency)

Comments:

Section C: Will the results help locally?

10. Can the results be applied to the local population?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider whether
- a cohort study was the appropriate method to answer this question
- the subjects covered in this study could be sufficiently different from your population to cause concern
- your local setting is likely to differ much from that of the study
- you can quantify the local benefits and harms

Comments:

11. Do the results of this study fit with other available evidence?

Yes ☐
Can't Tell ☐
No ☐

Comments:

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12. What are the implications of this study for practice?

Yes	
Can't Tell	
No	

HINT: Consider
- one observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making
- for certain questions, observational studies provide the only evidence
- recommendations from observational studies are always stronger when supported by other evidence

Comments:

Lampiran 4

Surat Pernyataan Bebas Plagiasi

SURAT PERNYATAAN BEBAS PLAGIASI

Saya yang bertanda tangan dibawah ini :

Nama : Hanny Mutiarayni Balga

NIM : 1710211065

Program Studi : Kedokteran Program Sarjana

Dengan ini menyatakan bahwa judul karya tulis ilmiah "Peningkatan Kadar Enzim Transaminase sebagai Prediktor Diabetes Melitus Tipe 2 pada Pasien Perlemakan Hati Non Alkoholik- *Literature Review*" benar bebas dari plagiarism, dengan skor 24%. Apabila pernyataan ini terbukti tidak benar maka saya bersedia menerima sanksi sesuai ketentuan yang berlaku.

Demikian surat pernyataan ini dibuat untuk dipergunakan sebagaimana mestinya.

Jakarta, 27 Januari 2021,
Yang Menyatakan,

Dosen Pembimbing

(dr. Tuty Rizkianti, Sp.PK)

(Hanny Mutiarayni Balga)

PENINGKATAN KADAR ENZIM TRANSAMINASE SEBAGAI PREDIKTOR DIABETES MELITUS TIPE 2 PADA PASIEN PERLEMAKAN HATI NON ALKOHOLIK LITERATURE REVIEW

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